HOUSE OF COMMONS SESSION 1994–95

HEALTH COMMITTEE

Third Report

BREAST CANCER SERVICES

Volume I

Report, together with the
Proceedings of the Committee

Ordered by The House of Commons *to be printed*
6 July 1995

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The Health Committee is appointed under Standing Order No. 130 to examine the expenditure, administration and policy of the Department of Health and associated public bodies.

The Committee consists of 11 Members. It has a quorum of three. Unless the House otherwise orders, all members nominated to the Committee continue to be members of it for the remainder of the Parliament.

The Committee has power:

(a) to send for persons, papers and records, to sit notwithstanding any adjournment of the House, to adjourn from place to place, and to report from time to time;

(b) to appoint specialist advisers either to supply information which is not readily available or to elucidate matters of complexity within the Committee's order of reference;

(c) to communicate to any other committee appointed under the same Standing Order (or to the Committee of Public Accounts and to the Deregulation Committee) its evidence and any other documents relating to matters of common interest;

(d) to meet concurrently with any other such committee for the purposes of deliberating, taking evidence, or considering draft reports.

The membership of the Committee since its nomination on 13 July 1992 has been as follows:

Mrs Marion Roe was elected Chairman on 15 July 1992

Mr John Austin-Walker *(added 12.12.94)*
Mr Michael Bates *(added 6.12.93 and discharged 27.6.94)*
Mr Hugh Bayley *(added 26.10.92)*
Mr Roland Boyes *(discharged 26.10.92)*
Mr James Clappison *(discharged 24.1.94)*
Mr David Congdon
Mr Iain Duncan Smith *(added 24.1.94)*
Mr Jonathan Evans *(added 27.6.94 and discharged 28.11.94)*
Mr David Hinchliffe *(discharged 26.10.92)*
Tessa Jowell *(added 26.10.92 and discharged 12.12.94)*
Mr Robert Key *(added 28.11.94 and discharged 1.5.95)*
Mrs Jacqui Lait *(discharged 6.12.93)*
Alice Mahon
Mr Roger Sims
Rev Martin Smyth
Mr Richard Spring *(added 1.5.95)*
Mr Michael Trend *(discharged 5.7.93)*
Mr John Whittingdale *(added 5.7.93)*
Audrey Wise

The cost of printing and publishing this Report is estimated by HMSO at £5650.

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THIRD REPORT

BREAST CANCER SERVICES

The Health Committee has agreed to the following Report:

I. INTRODUCTION

1. It is now four years since the publication of *The Health of the Nation*.[1] The White Paper set out a firm commitment to a series of objectives and targets for improvements in health by the year 2000, including a reduction in death and ill-health from cancers.[2] The *Health of the Nation*'s target for breast cancer[3] was

> "to reduce the rate of breast cancer deaths among women invited for screening by at least 25% by the year 2000."[4]

This would mean a reduction from 93.6 deaths per 100,000 population in 1990 to no more than 72.2 per 100,000 in 2000, or the prevention of 1,250 deaths per year.[5]

2. As nearly half the time between the publication of *The Health of the Nation* and the date for the achievement of the breast cancer target has elapsed,[6] we felt that this would be an appropriate time to examine the progress made so far in achieving the target and ways in which that progress might be accelerated. With the recent publication of several important reports on the subject from the Expert Advisory Group on Cancer to the Chief Medical Officers,[7] the British Breast Group,[8] the British Association of Surgical Oncology Breast Cancer Surgeons,[9] and the Cancer Relief Macmillan Fund[10] — we also felt that we would be well placed to make a contribution to the current debate.

3. The terms of reference we set ourselves were to consider "ways in which the quality and availability of breast cancer services in the UK might be improved". We decided to concentrate on three areas of particular importance:

- the progress made by the NHS Breast Screening Programme towards meeting the government's target of reducing the number of deaths from breast cancer by 25 per cent by the year 2000, and the factors influencing the uptake and success of the programme;
- the role of clinical trials in evaluating promising new treatments, and ways in which more women with early breast cancer might be recruited to these trials; and
- the proposed role of Primary Care Teams, Designated Cancer Units and Designated Cancer Centres; and of Specialist Breast Units in the provision of high quality breast cancer care.

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[1] *The Health of the Nation*, Cm 1523, June 1991.

[2] Ibid, p63.

[3] Malignant neoplasm of the female breast (*International Classification of Diseases* 9, No 174).

[4] *Health of the Nation Key Area Handbook: Cancers*, Department of Health, January 1993, p95.

[5] Ibid.

[6] Whilst the *Health of the Nation Target* was first published in 1991, targets were established for a reduction in breast cancer deaths for the NHS Breast Screening Programme in 1987.

[7] *A Policy Framework for Commissioning Cancer Services* (Department of Health, April 1995).

[8] *Provision of breast services in the UK: the advantages of specialist breast units* (British Breast Group, July 1994)

[9] *Guidelines for Surgeons in the management of Symptomatic Breast Disease in the United Kingdom* (British Association of Surgical Oncology, December 1994) and *Quality Assurance Guidelines for Surgeons in Breast Cancer Screening* (NHSBSP, November 1994).

[10] *The Macmillan Directory of Breast Cancer Services in the UK* (Cancer Relief Macmillan Fund, February 1995).

4. In December 1994, we wrote to various interested parties seeking memoranda, and issued by press notice a general invitation to submit evidence. In March and April of this year, we took oral evidence from representatives of the British Breast Group (BBG), the British Association of Surgical Oncology (BASO), Dr Gwyneth Vorhaus, the National Health Service Breast Screening Programme (NHSBSP), the UK Co-ordinating Committee on Cancer Research (UKCCCR), the Cancer Research Campaign Clinical Trials Centre, the Clinical Trials Support Unit and the ICRF/MRC Cancer Studies Centre of the University of Oxford, Radiotherapy Action Group Exposure (RAGE), the Cancer Relief Macmillan Fund, Marie Curie Cancer Care, Baroness Cumberlege, Parliamentary Under Secretary of State for Health, Dr Kenneth Calman, the Department of Health Chief Medical Officer, Professor Karol Sikora of the CMO's Advisory Committee on Cancer Services and Mr Chris Spry of South Thames Regional Health Authority.

5. The Committee received over 90 memoranda of evidence from more than 70 individuals and organisations, including patients, doctors, nurses, radiographers, researchers, charities and others. We would particularly like to express our thanks to our specialist advisers, Professor Michael Baum MD(hc) ChM FRCS of the Institute of Cancer Research at the Royal Marsden Hospital and Professor Roger Blamey MD FRCS of the City Hospital, Nottingham.

6. This Report is set out as follows. First we consider the incidence of breast cancer and breast cancer mortality in Britain, and how they compare with those in other parts of the world. Then we look at the contribution made by the NHS Breast Screening Programme to the early detection of breast cancer and the effect of early detection on survival rates. Next we examine the way in which treatment is provided both for women with symptomatic breast cancer and for women who have abnormalities detected by the NHS Breast Screening Programme, and the ways in which the delivery of such treatment might be improved. We also look at the proposed new policy framework for commissioning cancer services,[11] and examine its likely effects on the provision of breast cancer care. Finally, we assess the role of clinical trials in developing new treatments for breast cancer, and we make recommendations about how the progress of good clinical research might be expedited. A summary of our conclusions and recommendations is provided at pages lviii to lxii.

II. BREAST CANCER INCIDENCE AND MORTALITY

7. In 1992, 13,663 women in England and Wales died as a result of breast cancer. This accounted for 4.8 per cent of all female deaths — more than were caused by any other cancer, or any other disease, with the exception of coronary heart disease and cerebrovascular disease.[12]

8. In general, the incidence of breast cancer is higher in wealthier countries, women in North America and Western Europe being at highest risk of developing the disease.[13] Incidence rates amongst women migrating from low- to high-risk countries approach the level of the new country in second and subsequent generations, which suggests that social and environmental factors may be responsible in part for international differences in incidence rates.[14] It is, as one witness told us, "a disease of civilisation ... rates seem to follow civilisation and development."[15]

9. International comparisons of the incidence of breast cancer should be treated with caution, as methods of registering new diagnoses and causes of death vary considerably from country to country.[16] Nonetheless, it is possible to say with some certainty that Britain does

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[11] *A Policy Framework for Commissioning Cancer Services* (Department of Health, April 1995).

[12] *Official Report*, 26 October 1994, *cc850-1w.*

[13] Q4.

[14] Ev p157.

[15] Q58.

[16] See paragraphs 21 to 24.

not have a particularly high, or a particularly low, incidence of the disease when compared with other OECD countries.[17]

10. Between 1983 and 1987, the world standardised incidence rate of breast cancer in England and Wales was 56.10 cases at all ages per 100,000 population, and in Scotland, the comparable figure was 62.60.[18] This is lower than in the USA (89.20 amongst white Americans, 65.00 amongst black Americans), the Netherlands[19] (72.70), Canada (71.10), Iceland (69.70), Denmark (68.60), France[20] (66.20), Italy[21] (65.40) and New Zealand (64.30 amongst non-Maoris and 64.00 amongst Maoris).[22]

11. However, the incidence of the disease is rising in the UK. In 1983 there were 21,296 registered diagnoses (110.03 per 100,000 population over the age of 15), and in 1989, there were 28,029 (131.48 per 100,000 population over the age of 15). The Department of Health estimates that in 1992 there were 30,056 new cases of breast cancer, or 140.51 per 100,000.[23] This reflects an international increase in the incidence of breast cancer, and we have been told that it is less marked than the increases in some other countries.[24] The NHS Breast Screening Programme has undoubtedly contributed to this increase in recorded incidence, by detecting more cancers before they would otherwise have become apparent.

12. The Department of Health has also supplied us with information which shows that there are significant geographical variations in the incidence of breast cancer within this country. In 1989, the overall incidence of breast cancer in England and Wales (as distinct from the UK as a whole) was 107.1 new cases per 100,000. In many Regions, such as the West Midlands, Mersey and South East Thames, the incidence is close to the national, overall figure. However, in Oxford, 89.3 people per 100,000 were registered as having breast cancer in 1989, whilst in Wessex, the equivalent figure was 133.1.[25] The Department of Health was unable to offer a firm explanation of for these variations, although they are "crude" incidence rates (i.e. they are not weighted for the age structure of the population), and regional differences in the age structure of the population will therefore lead to differences in the incidence of breast cancer.[26]

13. The rate of change of incidence rates also varies substantially from region to region. Between 1979 and 1989, the breast cancer incidence rate in England and Wales increased by 28 per cent overall. However, between regions, this varied from a 47.2 per cent increase in Wessex to an increase of only 3.2 per cent in Trent. North East Thames recorded a 71.6 per cent increase over this period, but the Department told us that the baseline figure for 1980 from which this increase was calculated was "known to be deficient".[27] A high percentage increase in regional breast cancer incidence over this period was not necessarily associated with high incidence rates. Although the incidence of breast cancer in Mersey in 1989 was 108.8 cases per 100,000 (only 1.7 per cent higher than the national overall rate), the increase since 1980 was 41.3 per cent (13.3 per cent higher than the overall increase).[28] In the South Western Region, the increase in the incidence rate of breast cancer over the same period was 22.2 per cent (smaller than the overall increase), although the incidence rate in that Region was higher than the overall national figure.[29]

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[17]With the exception of Greece, Turkey, Luxembourg, Austria and Belgium, for which no data are available [see Ev p166].

[18]Ev p166.

[19]Eindhoven.

[20]Bas-Rhin.

[21]Florence.

[22]Ev p166, Table 3.

[23]Ev p163.

[24]Ev p157.

[25]Ev pp238-43.

[26]Ibid.

[27]Ibid.

[28]Ibid.

[29]Ibid.

14. Most of our witnesses agreed that very little is known about the reasons for international and regional differences in the incidence of breast cancer or about the reasons for the rising incidence rate,[30] although there was general agreement that genetic, as well as environmental factors played a part. Researchers have recently identified a gene, BRCA1, mutations of which can cause some breast cancers,[31] and women with a family history of breast cancer are known to have a higher risk of developing the disease themselves.[32]

15. We heard a number of suggestions about environmental and social risk factors, and many witnesses were confident that reproductive factors, including late childbearing, childlessness, and the use of oral contraceptives, were significant.[33] Other possible factors which were cited included a high fat diet,[34] ionising radiation,[35] early abortion,[36] smoking[37] and the pesticide, Lindane.[38]

16. It is clear that the aetiology of the disease is not yet sufficiently well understood to enable any systematic method of reducing mortality by primary prevention to be used clinically, although the International Breast Intervention Study (IBIS), which began in July 1993, is testing the effectiveness of daily doses of tamoxifen in preventing breast cancer in women who are identified as having at least a high (at least two-fold) risk of the disease. However, results from the study are not expected for some time.[39] If tamoxifen proves to be an effective preventative agent, its widespread use in high-risk women would reduce the incidence of the disease to some extent. In the case of some other diseases such as lung cancer and skin cancer, it is possible to attempt to reduce mortality from the disease by reducing identified, well-understood risk factors such as smoking and exposure to the sun. **It is therefore all the more important to ensure that, in the case of breast cancer, adequate facilities for early detection and appropriate treatment are available.**

17. Although the UK does not have a particularly high incidence of breast cancer when compared to other countries, it has almost the highest recorded breast cancer mortality rate in the world. In 1992, there were 39.47 deaths from breast cancer per 100,000 population in the UK, higher than any OECD country except Denmark, and higher than many countries in which the recorded incidence is higher.[40] The USA, for example, has a breast cancer incidence of 89.20 per 100,000 members of the white population and 65.00 amongst per 100,000 members of the black population, yet only 34 people in 100,000 die from breast cancer, fewer than in the UK.[41]

18. Like the incidence of breast cancer, breast cancer mortality varies from region to region within the country. In 1993, the crude death rate per 100,000 population in England was 49.27. However, the rate varied from 55.62 deaths per 100,000 population in East Anglia to 42.66 in Oxford.[42] The Department of Health told us that the number of breast cancer deaths rose to a peak in 1989, and has been falling since then.[43] Figures published by the Imperial Cancer Research Fund show that the breast cancer mortality rate suddenly began to

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[30]See, for example, QQ4, 5, 58 & 319-23.

[31]Ev p160, para 29 & Q325.

[32]QQ58 & 326; Ev pp157 & 243.

[33]Ev p157, para 2; Ev p243.

[34]Ev p157.

[35]Ev pp201-2.

[36]Ev p199.

[37]Bennike, Conrad, Sabore and Sørensen, Cigarette smoking and breast cancer, *BMJ* vol 301, p1431.

[38]QQ320-2.

[39]Ev pp48 & 61; *IBIS Protocol* (UKCCCR, 1994).

[40]Ev p165, Table 2.

[41]Ev pp164-5.

[42]Ev p238.

[43]Ev p242.

fall in about 1989.[44] The number of breast cancer deaths per 100,000 women aged 20 to 79, standardised to 1993 population, has fallen by about 10 per cent since the middle to late 1980s. The decline has been greater in younger than in older women: the mortality rate has decreased by 14 per cent in women aged 20 to 49, 11 per cent in women aged 50 to 69 and 5 per cent in women aged 70 to 79.[45] It is unlikely that this recent reduction in mortality is a result of the NHS Breast Screening Programme, as no reduction in mortality from screening is expected until 1997, although it may be a result of improvements in treatment, notably the wider use of adjuvant systemic therapies (an adjuvant systemic therapy is a treatment such as chemotherapy or tamoxifen, which is used in combination with surgery and works throughout the patient's whole body) [see paragraphs 107 and 132]. However, the UK's breast cancer mortality rate is still one of the highest in the world.[46]

19. Dr Richards of the British Breast Group suggested three possible explanations for our high recorded mortality rate. It might be the result of a "reporting bias" — differences in the way that data is collected from one country to another, it might be that the disease is for some reason more aggressive in this country and it could be because of differences in the way that the disease is treated in this country.[47] The difficulty lies in ascertaining the relative importance of each of these factors in contributing to the UK's high level of recorded breast cancer mortality.

20. Professor Martin Vessey of the Advisory Committee on Breast Cancer Screening and the Chief Medical Officer told us that mortality data tended to be very accurate but the quality of data on incidences tended to vary from country to country, as it was dependent on the system of cancer registration which was generally not as comprehensive as arrangements for registering causes of death.[48] However, other witnesses suggested that mortality data may vary from one country to another.[49] One possible explanation for the UK's high mortality rate in the face of only moderate incidence could therefore be that the real incidence is higher than the recorded incidence, and that the UK in fact has a comparatively high real incidence, which would account for the high mortality. Another would be differences in the manner of recording causes of death — Britain may be better at recording cause of death than other countries, and so may appear to have a relatively high number of breast cancer deaths.

21. There has been a voluntary system of cancer registration covering the whole of England and Wales since 1962. There are 12 regional cancer registries, each of which supplies data to the Office of Population Censuses and Surveys (OPCS). This data is then aggregated to provide a national data-set for England and Wales. The registries operate independently and receive data from a variety of sources including hospitals, GPs and histopathology laboratories. OPCS provides the registries with copies of death certificates which mention cancer. The whole of Scotland was covered by the Scottish National Cancer Registry in 1959. There are five constituent regional registries which submit data to the National Registry, and registrations are mainly derived from hospital in-patient episodes.

22. England and Wales, and Scotland, are almost unique in having comprehensive, national systems of cancer registration. Denmark has had a national cancer registry since 1942, and the reporting of new cases has been compulsory since 1987. Finland has also had a national system of cancer registration since 1952, and notification has been compulsory since 1961.

23. Most other European countries have a piecemeal system of local cancer registries, the data from which is not compiled to produce a national data-set. France has several cancer registries, some of which specialize in specific cancers such as childhood cancers and digestive tract cancers. Germany has four regional registries, but only the Saarland Cancer

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[44]Beral, Hermon, Reeves & Peto, Sudden fall in breast cancer death rates in England and Wales, *The Lancet* vol 345, 24 June 1995.

[45]Ibid.

[46]Ev p165.

[47]Q4.

[48]QQ59 & 324.

[49]See, for example, Q4.

Registry is believed to provide reliable incidence data for an entire state, in this case the second smallest state in the Federal Republic. Italy has nine active cancer registries, but it is estimated that they only cover about 10 per cent of the population, and Spain's eight registries cover only 20 per cent of the population. Switzerland has six regional cancer registries, which have been operating for over 10 years, but they still only cover 50 per cent of the population.[50]

24. It is very difficult to tell how differences in the methods of registering new cases of cancer affect the relative accuracy of the available figures. It is impossible to tell, in those countries which only collect data for a part of the population, whether that part is truly representative of the whole. It is fairly certain, however, that recording differences do distort the international comparative picture, and that some caution should be exercised when comparing the incidence of and mortality from breast cancer in different countries.

25. The second possibility cited by Dr Richards was that the type of breast cancer which occurs in this country is more aggressive than in other countries. The fact that a higher than expected number of cancers have been discovered in women who have received a negative screen in the last three years lends some support to this view [see paragraphs 47 to 60].

26. We agree with Professor Vessey, who told us that there is no really satisfactory answer to the question of why mortality rates should apparently be so high in this country.[51] Breast screening has been available in the USA (albeit in a piecemeal fashion) for longer than in the UK and this might explain, to some extent, America's comparatively higher incidence and lower mortality [see paragraph 17]. **The most worrying explanation, however, would be that the UK's poor survival rates may be due, at least in part, to poor treatment of the disease.** We consider this possibility in more detail in Section IV.

27. It is very difficult indeed, on the strength of the available evidence, to make good comparisons between breast cancer mortality in the UK and in other countries. Mr Hugh Bishop of BASO told us that "there are a huge number of ways in which the data can be manipulated and we should not be so over-awed in this country that we are at the bottom of the league."[52] Nonetheless, we found widespread agreement amongst our witnesses that, even if the UK does not have the *highest* breast cancer mortality rate in the world, it has *one of the highest* rates.[53] **We believe that the Department of Health should commission research to establish how the UK's incidence and mortality rates compare with other countries, using a common method of measurement, and in particular to investigate the possibility that the disease in this country runs a more aggressive course than it does elsewhere.**

III. THE NHS BREAST SCREENING PROGRAMME

Introduction

28. Breast screening is "the performance of tests on apparently well women to detect those with unrecognised breast cancer"[54] The NHS Breast Screening Programme is at the centre of the Government's plans to reduce breast cancer mortality and the *Health of the Nation* target for reduced mortality is defined in terms of the population invited for screening by the Programme.

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[50]For a summary of the cancer registration arrangements in different European countries, see *Survival of Cancer Patients in Europe* (IARC, 1995).

[51]Q58.

[52]Q8.

[53]See, for example, QQ4, 5, 8, 58 & 319.

[54]*Breast Cancer Screening — Report to the Health Ministers of England, Wales, Scotland & Northern Ireland by a working group chaired by Sir Patrick Forrest* (HMSO, 1986), p11.

The Forrest Report

29. In July 1985, the then Minister of State for Health, Mr Kenneth Clarke, appointed a working group under the Chairmanship of Professor Sir Patrick Forrest

> "i. to consider the information now available on breast cancer screening by mammography; the extent to which this suggests necessary changes in UK policy on the provision of mammographic facilities and the screening of symptomless women; and
>
> ii. to suggest a range of policy options and assess the benefits and costs associated with them; and set out the service planning, manpower, financial and other implications of implementing such options."[55]

30. The Forrest Report, published in November 1986, found that advances in the treatment of breast cancer had achieved only modest increases in survival, one reason being that the effectiveness of the treatment was related to the stage at which the disease was detected,[56] and recommended that

> "the only way substantially to reduce the number of deaths from the disease is to detect it before the patient presents with symptoms".[57]

The Group drew their evidence for the efficacy of screening primarily from four overseas studies: the randomised controlled trial in the Health Insurance Plan of Greater New York (HIP), the randomised controlled trial in Ostergötland and Kopparberg Counties, Sweden (known as the Two Counties Study), and case control studies in Nijmengen and Utrecht.[58]

31. In the HIP trial, 62,000 women aged between 40 and 64 were recruited between December 1963 and June 1966. They were randomly assigned to one of two groups: the study group, who were offered screening by clinical examination and two-view mammography at the beginning of the study and then three more times at yearly intervals; and the control group, who were offered no screening. Ten years after entry to the trial, there were 30 per cent fewer deaths from breast cancer in the group who were screened than in the control group.[59]

32. The Two Counties Study recruited 132,590 women aged 40 and over between 1977 and 1981. The study group were offered single-view mammography on entry to the trial and then at 24 month intervals for women aged under 50 and at 33 month intervals for women aged over 50. In the first 7 years, breast cancer deaths were reduced by 31 per cent in the study group compared to the control group.[60]

33. The Nijmengen and Utrecht studies recruited 30,000 and 20,500 women respectively to receive screening, but did not recruit a control group. Women in the study group who died of breast cancer (46 in each study) were matched by age to "controls" in the general population. The Nijmengen study found a possibly reduction in mortality of 52 per cent and the Utrecht study found a reduction of 70 per cent.

34. Breast cancer starts in the milk-producing cells in the breast and in the cells lining the small milk ducts. There is a pre-invasive stage of the disease during which the malignant cells are confined within the duct system. This is followed by an invasive stage in which the cancer invades the surrounding tissues and may spread to local lymph nodes and to distant sites such as the bones, liver, lungs and brain. Although breast cancer may disseminate early

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[55]Ibid, p7.

[56]Op cit, para 1.3.

[57]Ibid.

[58]Forrest Report, Annex C.

[59]Forrest Report, paras C.1 ff.

[60]Ibid, paras C.2 ff & Nyström et al, Breast cancer screening with mammography: overview of Swedish randomised trials, *The Lancet* vol 341 No 8851.

in its natural history, the rate of growth varies considerably and in many women it will be several years before metastases (secondary cancers) appear in other sites. The logic behind breast cancer screening is that if the cancer can be detected in the pre-invasive stage, before any spread has occurred, the correct treatment is likely to be much more effective.

35. The Group considered three possible methods of preliminary screening: mammography (an X-ray of the breast), clinical examination (a physical examination of the breast by a doctor or nurse) and breast self-examination (a regular examination of the breast by the woman herself). On the strength of the evidence available at the time, they concluded that mammography alone should be the preferred option for basic screening, as it was the only method which was proven to reduce breast cancer mortality in women aged 50 and above when used alone, although they recommended that the other methods should be the subject of further assessment.[61]

36. One of the areas of concern which was raised with us was the criteria for selecting women for screening.[62] The Forrest Report recognised that the most important risk factor for breast cancer was age. The four overseas trials from which the Group drew their evidence had found no indication that screening women under the age of fifty led to any significant reduction in mortality in that age group, and one reason for this was the difficulties associated with reading the mammograms of pre-menopausal women.[63] The Report recommended that women aged over fifty should be "positively encouraged" to attend for screening, but women over the age of sixty-four should only be offered screening on request.[64] The reasons which were cited for the upper age limit were the low acceptance rates amongst women of this age, the increased chance of women of that age dying of other diseases and the fact that, although breast cancer was more common in women over 65 than in other age groups, it tended to be less aggressive in older women. We examine the question of the screening age in more detail in paragraphs 81 to 96 below.

37. The third and final issue surrounding the basic screen was the screening interval. The Forrest Report drew the conclusion that "until the optimum frequency has been determined ... the interval should be three years."[65] It recognised, however, that the interval should be kept under review. Ascertaining the optimum screening interval is a question of balancing the costs (including the cost to patients) of screening more frequently against the risks of screening less frequently.

38. The screening programme proposed by Forrest was divided into four stages: the basic screen (mammography), to detect any abnormalities, which may or may not be cancer; the assessment of the abnormality, to determine whether a surgical biopsy is required; the surgical biopsy and the histological examination of the removed tissue; and the treatment of the screen-detected cancers.[66] Breast cancer screening consists of all the stages necessary to diagnose the disease, and not simply the mammography.[67] The Report therefore recommended that further assessment should be carried out by specialist assessment teams consisting of a clinician, a radiologist, a pathologist, a radiographer, a nurse and a receptionist. The advantages of a specialist assessment team would be the continued sharing of experience and review of cases in a multidisciplinary team; the immediate co-ordination of clinical, radiological and pathological findings, and that fine needle aspiration cytology (FNAC), where it was appropriate, could be carried out at the woman's first visit to the clinic. FNAC is a technique which involves drawing off some cells from the suspicious part of the breast through a very fine needle so that they can be examined under a microscope.

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[61] Ibid, pp21-5.

[62] See for example Ev pp 118-25.

[63] Forrest Report, p26; Q93.

[64] Ibid, para 5.7.

[65] Op cit, para 5.18.

[66] Forrest Report, p17.

[67] *Consolidated Guidance on Breast Cancer Screening* (NHSBSP, 1990).

The Organisation of the Programme

39. The Government accepted the proposals of the Forrest Report in February 1987, and implemented the programme over a three-year period to allow time for staff training and to provide facilities for treatment, counselling and aftercare. The UK was the first country in the European Community and one of the first in the world to have a national breast screening programme.[68] The initial cost of establishing the Programme was £70 million in the UK as a whole, and the total budget for purchasing screening services is currently about £37 million per year.[69] The Programme consists of four main "branches": providers, including screening units, assessment clinics and treatment centres; District Health Authority (DHA) purchasers; Regional Quality Assurance Reference Centres (QARCs) and the office of the National Co-ordinator.

40. DHAs are responsible for purchasing screening for their local populations, and the funds for running the Programme are now built into their allocations. The Forrest Report recommended that each unit should cover a population of 41,150 women in the target age group, within a total population of nearly half a million.[70] This is about two to three times the population of the average DHA, so each screening unit will have more than one purchaser.

41. Purchasing was originally undertaken by Regional Health Authorities (RHAs) and was therefore closely linked with the regional quality assurance programmes. There was some concern within the Programme about the transition from regional to district level purchasing at the time of the *Working for Patients* reforms, and the possibility that DHAs might opt out of consortia and set up their own screening programmes was seen as "a threat to quality".[71] Eventually, however, the integrity of the Programme was maintained by retaining the quality assurance teams at RHA level.[72]

The Quality Assurance Programme

42. The Forrest Report recognised that, if breast screening were to be successful, it would be necessary to provide a high quality service, and to that end laid down guidelines on the basic screen, assessment and follow-up.[73] The NHS Breast Screening Programme Quality Assurance Programme (QAP) was established to ensure that the same high quality service was available to women throughout the country.

43. The Quality Assurance Programme works at three levels: national, regional and local (in the screening unit).[74] The Department of Health is responsible for defining the aims and objectives of breast screening, the standards of the Programme and the general management structure.[75] The Department also provides funding for the work of the Programme and the office of the National Co-ordinator and her staff. RHAs are responsible for purchasing quality assurance and, through Regional Quality Assurance Reference Centres, for ensuring that DHAs purchase a level of service which adheres to the Department's national specifications. In 1992, the Chief Executive of the NHS Management Executive described the national specifications as "non-negotiable" and told the Committee of Public Accounts that "we do not expect ... districts to tinker with the specification ... if there are purchasers that want to try to step out of line they must be brought back into line by the regions. That is the role of the region and we have made that extremely clear."[76]

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[68]Ev p157.

[69]Q117.

[70]Op cit, p44.

[71]*Breast Cancer Screening 1991: Evidence and Experience since the Forrest Report* (NHSBSP, 1991).

[72]Ev p214.

[73]Op cit, Annex F.

[74]Q113.

[75]Ev pp214-15.

[76]Committee of Public Accounts, Cervical and Breast Screening in England, Minutes of Evidence, Wednesday 4 March 1992 (HC 333-i, 1991-92), p15.

44. RHAs are required to have a nominated manager with responsibility for quality assurance who normally has a few sessions a week allocated to the role, and to have a QARC, typically staffed by a Quality Assurance Co-ordinator, a clerk and a data officer.[77] Originally there were 14 QARCs, but two have already been combined into one and other merged Regions may follow suit.[78] The Quality Assurance Manager is supported by a quality assurance team — a multidisciplinary group of professionals each of whom takes particular responsibility for his or her own area of expertise. Regional quality assurance teams have no formal powers to enforce national standards on purchasers, but can advise the Regional Director of Public Health when a purchaser appears to be moving out of line. It is the Regional Directors' responsibility "to ensure continued co-ordination of designated health programmes (such as breast cancer screening ...)."[79] The cost of the QAP at national level is only 1.5 per cent of the entire screening budget — about half a million pounds, and at Regional level, less than seven per cent of the budget.[80]

45. In addition to stringent national guidelines on the minimum standard of service which is to be purchased, there is a wealth of other guidance available to purchasers and providers of breast screening. The Forrest Report acted as the template for the Programme, and contained detailed recommendations about methods of screening and assessment and the organisation and requirements of the service, and the NHS Breast Screening Programme has subsequently produced substantial guidance on various aspects of screening which is available to purchasers and to quality assurance teams. In October 1994, there were over 30 NHSBSP publications of this kind.[81]

46. The National Co-ordinator of the NHS Breast Screening Programme, Mrs Julietta Patnick, told us that the Quality Assurance Programme "has been and remains one of our strengths, we pride ourselves on it, we are acknowledged around the world as a gold standard and the National Audit Office, in their report some years ago, marked it as one of our great strengths."[82] She argued that quality assurance could not be left to individual screening units, as some screening units tended to present persistent problems which "one suspects would not be dealt with if that unit were left to its own devices".[83] Another advantage of the QAP operating at a supra-unit level is that it enables the performance of one screening unit to be compared to that of another.

47. The Quality Assurance Programme is also able to pick up problems at a national level. Last year, it became apparent that a higher than expected number of cancers were being detected in the period between screens and it was believed that this was a result of existing cancers not being detected by the screening method which had been used since the inception of the Programme. In order to increase the number of cancers being detected at an early stage, the Department of Health announced three changes to the Screening Programme: two mammograms, rather than one, would be taken of each breast on the first occasion when a woman attended for screening; the optical density (contrast) of mammograms would be increased and focused clinical update training would be provided for radiologists.[84] It is highly unlikely that a widespread problem such as this would have been picked up by a quality assurance programme operating only at a local level. We discuss these changes in more detail in paragraphs 60 to 61 below.

48. There is a further advantage to operating quality assurance at a supra-district level: as well as ensuring that screening units are meeting their contractual requirements, regional quality assurance teams are able to act as a check on purchasers, to ensure that the service

[77]Department of Health Circular HC(89)6.

[78]Ev p214.

[79]NHS Executive Letter, EL(95)31.

[80]Q113.

[81]Ev p216.

[82]Q113.

[83]Ibid.

[84]*Official Report*, 16 January 1995, *c311w*.

which is being contracted for meets the required standard. The National Co-ordinator told us that:

> "we have occasionally attempted to influence purchasers in the direction in which they are hoping to purchase. For example, if they were going to go out to competitive tender we would not wish them to purchase mammography alone; it is important that screening is seen as a complete package ... You cannot pick out a bit and say, right, we are going to look and see if we can get that somehow cheaper, and there have been one or two instances of that."[85]

One problem had arisen when a purchasing authority had to be convinced that it was inappropriate to have laboratory technicians reporting cytology samples from women recalled for assessment, and another had not been ensuring that results letters were sent out to women. In the latter case, the National Co-ordinator had to intervene personally.[86]

49. The introduction of two-view mammography has led to further tension between purchasers and quality assurance teams. The Department of Health made it clear that the two-view mammogram should be implemented "as quickly as possible, and certainly no later than 1 August 1995,"[87] and some purchasers have taken this form of words as a licence not to implement the second view *until* August. The Department estimated that the cost of the second view would be on average about £10,000 per unit per year, but some purchasers have refused to provide the extra funding, insisting that the increased cost must be met from savings elsewhere. The National Co-ordinator told us of one programme which had only half the national recommended radiographer staffing level, and was refusing to provide extra funds to make up this shortfall, let alone introduce the second view.[88]

50. **We believe that the Quality Assurance Programme is one of the great strengths of the NHS Breast Screening Programme. One of the most important aspects of the Quality Assurance Programme is its three-tiered operation at national, regional and local level.**

51. However, it is still unclear what arrangements will be introduced for the provision of quality assurance after the abolition of RHAs. The National Co-ordinator told us that she was concerned about the relationship between quality assurance teams and purchasers following the proposed move in April 1996 from RHAs purchasing quality assurance to DHA "lead purchasers". This means that DHAs would form into consortia, possibly involving all the health authorities in an old Region, or possibly with a larger or smaller number of authorities, with one DHA purchasing quality assurance on behalf of the others. She told us that

> "quality assurance is not a purchaser inspectorate. Rather, it stands aside from purchaser and provider monitoring both identifying problems and taking action where necessary."[89]

One of the functions of the QAP is to keep purchasers, as well as providers, in line with national standards. The danger is that DHAs and DHA consortia will soon be responsible for purchasing the services of the quality assurance teams which, until now, have been striving to ensure that they were purchasing a high quality screening service. In effect, DHAs will be purchasing services for monitoring their own purchasing.

52. The National Co-ordinating Group of the Regional Quality Assurance Managers was so concerned about the threat posed to the QAP by the dissolution of the Regions that they instructed their Chairman, Dr Nicholas Perry, to contact the Chief Medical Officer. His letter is worth quoting at length:

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[85] Q119.

[86] Ev pp213-5.

[87] NHS Executive Letter, EL(95)7.

[88] Ev pp213-5.

[89] Ibid.

> "The Quality Assurance Managers believe that the mechanisms currently in place for Quality Assurance are commendable. Regional variations in delivery and strength of Quality Assurance should be resisted ... To ensure equitable delivery of standards, it is vital to maintain and if possible strengthen the strong co-ordinating role held by the NHSBSP. If this cannot be achieved by central control of purchasing of QA, lead district purchasing must be supported by sufficiently strong mechanisms of co-ordination and accountability to the National Programme."[90]

The Chief Medical Officer replied that "the need for strong central co-ordination of Quality Assurance in the Breast Screening Programme is, and will continue to be, a high priority".[91] A further point which Dr Perry raised in his letter was that many members of quality assurance teams are principally employed by provider units and work part time for the regional QA team. It is therefore all the more important that there is strong, central guidance for quality assurance teams, in order to avoid any allegations of bias.[92]

53. **We believe that it is vital to preserve the NHSBSP Quality Assurance Programme and the Office of the National Co-ordinator in something like their present form following the dissolution of the Regions next April.** There is a serious danger that, under a system of lead district purchasing, the QAP will turn into a contract enforcement programme — checking that provider units are providing the service which they are contracted to provide, without ensuring that the service which is being purchased meets the national specifications in the first place. In order to provide that requisite level of expertise in the QAP, it is necessary to draw members of quality assurance teams from screening and assessment units, and strong, central guidance for QA teams is the only way of ensuring that their independence is above reproach.

54. **The NHS Breast Screening Programme Quality Assurance Programme will only continue to be effective if its independence from the purchasers and providers of breast screening services is preserved. Lead district purchasing of the QAP is therefore potentially problematic, and the Department of Health must ensure that, if the transition to lead district purchasing is made in April 1996, quality assurance teams remain accountable to the national Programme rather than to their new purchasers. Even so, a system in which accountability does not follow funding is likely to be unnecessarily complicated, bureaucratic and unwieldy. We therefore recommend that the Department of Health give serious consideration to funding the QAP either directly by the NHS Executive, or by bottom-slicing from DHA allocations, and setting mandatory requirements for the standard of quality assurance which is to be purchased.**

Problems with the Programme

55. Mrs Hazel Thornton, a co-opted member of RAGE and a founder member of the Consumer's Advisory Group on Clinical Trials described the Programme as

> "costly trawling of a limited asymptomatic public group ... creating huge ... psychological and physical morbidity"[93]

She argued that it had achieved no significant reduction in mortality to date, had been introduced "without benefit of risk-limiting trial evaluation, informed consent or balanced information to invitees (who do not understand what they have agreed to)." Her final criticism was that ductal carcinoma in situ (DCIS) (a non-invasive, pre-cancerous growth) was diagnosed in a significant proportion of women, who were labelled as having cancer and received surgical treatment, although DCIS would not progress to being an invasive cancer during the lifetime of 75 per cent of these patients.[94] Her main point was that the resources

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[90] Ev p218.
[91] Ibid.
[92] Ibid.
[93] Ev p111.
[94] Ibid.

invested in the Screening Programme could be better spent on improving the management of women with symptomatic cancer, although she was not sure exactly where the money should be spent.[95]

56. Although there is some merit in Mrs Thornton's criticism, we do not believe that it is entirely fair: the Programme was introduced on the strength of evidence from randomised controlled trials, which showed a significant reduction in mortality [see paragraphs 30 to 33]. Furthermore, it is well understood that the lead time of the Screening Programme is such that no reduction in population mortality from breast cancer is likely to be observed until about 1997, ten years after its introduction. However, we do believe that there are adverse consequences associated with breast screening which should be examined, principally the anxiety experienced by those women who are referred for further assessment following the basic screen, and the problems associated with the management of ductal carcinoma in situ.

False Positive Recalls

57. Following a basic screen, a woman will have to wait up to two weeks for the result. Since the Programme started in 1987, five million women have been screened, and about 20,000 cancers have been detected. A total of about 270,000 women have been recalled for further assessment, so about 250,000 women who did not have cancer have been recalled.[96] In 1992-93, the last full year for which figures are available, 1,165,726 women attended for basic screening. Of these women, 63,076 were recalled, 9,129 received biopsies and 6,597 were diagnosed as having breast cancer.[97] This means that for every cancer which was detected by the Programme, nearly ten women who did not have cancer were recalled, many of whom will have had some form of benign breast disease, and some of whom will have received "false positive" results — a mammogram which appears to show a breast abnormality when none is in fact present. We believe that the anxiety experienced by these women is a matter for concern and we agree with the National Co-ordinator, who described it as "a recognised downside ... to screening."[98] False positive mammograms are not only a source of anxiety, but they lead, in a few cases, to women undergoing unnecessary clinical investigations, including diagnostic surgery.[99] The NHS Breast Screening Programme is sensitive to this problem and the National Co-ordinator described some of the steps which they have taken to reduce this kind of anxiety. They ensure that the recall letter does not arrive at the woman's home on a Saturday, when she is less likely to be able to seek advice and support from her own GP, and that the time between sending the letter and the appointment for assessment is only "a matter of days".[100] **We believe that these are sensible precautions.** The Cancer Research Campaign has recently completed a study, funded by the NHSBSP, of women's needs at assessment, including their written information needs, and will shortly be able to publish guidance.[101] It should also be emphasised that the recall rate is already falling, from 6.2 per cent in 1991-2 to 5.7 per cent in 1992-3. This may be due largely to increasing expertise amongst professionals involved in the Programme.

58. Witnesses from the Department of Health painted a rather more worrying picture. They told us that in some cases, an assessment clinic would detect an abnormality which was not believed to be breast cancer and the woman would be placed on "early recall". This means that she would be asked to come back after a period of 6 to 12 months for another X-ray. Professor Sikora explained that a comparison of the two pictures, taken several months apart, would allow the radiographer to reach a firmer conclusion on whether the abnormality was cause for concern.[102] This can only be a source of tremendous anxiety for the woman who,

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[95]QQ239-43.

[96]Ev p32 & QQ84-9.

[97]*NHS Breast Screening Programme review 1994*, p17.

[98]Q87.

[99]Wright & Mueller, Screening mammography and public health policy: the need for perspective, *The Lancet*, vol 346, p29.

[100]Q88.

[101]Ibid.

[102]Q353.

after being recalled and told that she appears to have an abnormality of her breast, which may or may not be malignant, has to wait several months for confirmation either way. We do not believe that the early recall of women with ambiguous mammograms is a humane policy. There is evidence that 30 per cent of women with breast cancer develop an anxiety state or a depressive illness within a year of diagnosis, and there is no reason to suppose that a woman who thinks she might have cancer will be significantly less prone to such problems.[103] The Chief Medical Officer mentioned that the anxiety associated with early recall could be reduced by getting a second opinion of the mammogram from another radiologist or by reducing the recall period.[104] Professor Sikora told us that the results of an equivocal mammogram could be clarified within two days by performing a biopsy, but that this would come at an increased cost.[105] **We recommend that the NHS Breast Screening Programme examines, as a matter of urgency, ways in which patients who have breast abnormalities which are not believed to be cancer can receive a firm diagnosis more quickly, rather than be placed on early recall, and issues guidance to assessment units.**

59. We were interested to learn from Professor Vessey that many of the units which provide assessment services for women with screen-detected abnormalities are already offering "one-stop" assessment clinics, at which women who are recalled for assessment can undergo all the necessary investigations in a single visit.[106] Although such clinics do not affect the waiting time between basic screening, results or recall and assessment, the National Co-ordinator told us that they provide "clear benefits for the woman, in terms of minimising the anxiety associated with a suspicious lesion".[107] We believe that such clinics are a useful innovation, and that any move towards reducing the time which a woman with breast disease has to wait for a confirmed diagnosis is inherently desirable. We make recommendations about how "one-stop" diagnostic clinics could be further developed in Section IV.

The Recent Changes to the Programme

60. The Department of Health announced three changes to the basic screening method in January this year, in response to the news that a higher than expected number of cancers were appearing in the interval between screens [see paragraph 47].[108] It is possible that this is a result of the disease being more aggressive in this country than elsewhere [see paragraph 19]. The Forrest Group based their screening plan, including screening intervals and techniques, on evidence from overseas. If the disease in this country is more aggressive than in, for example, Sweden or the USA, it may be that more genuine interval cancers are occurring in the UK Programme than would be expected on the strength of evidence from those countries. The other possibility is that the interval cancers are in fact the result of "false negatives" — cancers which were present, but not detected at screening and which were subsequently diagnosed between screens after they had grown and possibly progressed to a more advanced stage. The changes to the screening method will not have any impact on the number of "true" interval cancers, but they may have an impact on the number of "false negatives" — cancers which are present, but undetected, at screening and express themselves during the screening interval.

61. We hope that these improvements to the sensitivity of the test (that is, its ability to detect cancers) may also have a beneficial effect on the specificity of the test (that is, its ability to exclude patients who do not have breast cancer), reducing the number of false positives and equivocal mammograms and reducing the number of women being recalled for assessment. **We congratulate the Department of Health on its swift response to the higher than expected number of interval cancers, and we hope that both the number of false negatives and the number of false positives (and therefore the recall rate) will fall in**

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[103]Maguire P, ABC of Breast Disease: Psychological Aspects, *BMJ* 309, p1649.

[104]Q353.

[105]Ibid.

[106]Q91 & Ev p218.

[107]Ev p218.

[108]Woodman, Threlfall, Boggis and Prior, Is the three year breast screening interval too long? Occurrence of interval cancers in the NHS breast screening programme's north western region, *BMJ* vol 310, pp 224-6; *Official Report*, 16 January 1995, *c131w*.

future years as a result of these changes. Apart from a general reduction in the anxiety caused to women who are recalled, we believe that the changes will result in some cost saving, as fewer women will be referred for assessment, and we therefore find it even more puzzling that some DHAs have been reticent in introducing them [see paragraph 49].

Ductal Carcinoma in Situ

62. Another point raised by Mrs Thornton was the problem of ductal carcinoma in situ (DCIS). This is a non-invasive stage of breast cancer, which may or may not develop into invasive breast cancer during the woman's lifetime. Although it is widely agreed that DCIS is a risk factor for breast cancer, the level of that risk is disputed, but a trial of four approaches to its treatment — surgery alone, surgery with radiotherapy, surgery with tamoxifen and surgery with radiotherapy and tamoxifen — is currently being conducted, and this may shed more light on the nature of the disease.[109] The problem is that some women whose DCIS is detected by the Screening Programme will go on to have surgery, possibly with breast conservation or mastectomy followed by reconstruction, for a condition which might not otherwise have become life threatening or produced any symptoms at all during their lifetime.

63. There is very little which can be done about this problem at the moment. It is inevitable that, when a screening programme is aimed at detecting a disease in its early stages, and when the rate of progression of the disease varies from patient to patient, some people will receive treatment which is unnecessary insofar as it is directed at a condition which would not otherwise have caused them any problems. In the case of breast surgery, the treatment may also have negative aesthetic consequences and may affect the woman's body image and self-esteem.[110] This is unfortunate, as it is impossible to tell in advance whether a given case of DCIS will become invasive, but such costs of a screening programme must always be weighed against its benefits including, in this case, the benefit to women who, if their DCIS had not been detected at an early stage, would have developed invasive breast cancer. **We await the outcome of the DCIS trial with interest, and we note that the British Association of Surgical Oncology has already published guidelines, through the NHSBSP, for the management of screen-detected DCIS, based on the best available evidence at present. However, we recommend that, once the comparative outcomes of the treatments under investigation are established, the Department of Health should issue, through the NHS Breast Screening Programme, guidance on best practice for the management of the condition.**

The Effectiveness of the Programme

64. The success of the NHS Breast Screening Programme must ultimately be measured in terms of its effectiveness in reducing mortality from breast cancer. The National Co-ordinator told us that the reduction in mortality proposed in the *Health of the Nation* was "a clear focus towards which all activities of the Programme are directed." However, no reduction in mortality as a result of the Screening Programme is expected to become apparent until 1997.[111]

65. Since the publication of the Forrest Report, the new evidence which has emerged has tended to confirm the original view that screening by mammography is effective in reducing breast cancer mortality in women over the age of fifty. The results from randomised controlled trials such as the UK Trial of Early Detection in Breast Cancer (TEDBC) indicate a reduction in breast cancer mortality of about 25 per cent, while the results of case control studies such as the Florence Case Control Study indicate a reduction in mortality of over 50 per cent.[112] The difference between these findings may be due in part to the fact that the

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[109] *Protocol of the UK Randomised Trial for the Management of Screen Detected Ductal Carcinoma in Situ of the Breast* (NHSBSP, 1989).

[110] Maguire P, ABC of Breast Diseases: Psychological Aspects, *BMJ* vol 309 p1650.

[111] Ev p32.

[112] For a summary of these findings, see *Breast Cancer Screening 1991: Evidence and Experience since the Forrest Report* (NHSBSP, 1991).

randomised controlled trials were analysed on an "intention to treat" basis — that is, women who were invited for screening but did not attend were still counted as part of the study group — whereas the case control studies indicate the potential reduction in mortality amongst those women who actually attend for screening.

66. A further significant piece of evidence comes from the "Swedish Overview", published in 1993.[113] This is an overview of the evidence from the original Two Counties trial, taken together with smaller trials in Malmo, Stockholm and Gothenberg. This study confirmed the original findings of the Two Counties study, that a reduction in mortality of about 30 per cent was found in the study group. When broken down by age, it was found that the reduction in mortality amongst women aged 40 to 49 was a non-significant 13 per cent, and amongst women aged 70 to 74, it was only 6 per cent. However, in women aged 50 to 69, there was a reduction in mortality of 29 per cent in the study group when compared to the control group. According to Jocelyn Chamberlain of the Institute of Cancer Research, the Swedish Overview

> "has confirmed, beyond reasonable doubt, that breast screening between the ages of 50 and 69 reduces a woman's chances of dying from breast cancer over the ensuing twelve years by at least 25-30%"[114]

67. Even if breast cancer screening has been shown to be effective in trials, it remains to be seen whether the NHS Breast Screening Programme will be able to achieve the same impact on mortality as the teams working in research trials. One way of examining the success of the Programme to date is to examine interim indicators of its performance.

68. The NHS Breast Screening Programme collects and publishes data on various aspects of its work: the number of women who are screened, recalled and receive biopsies; the number of cancers detected and the number of small cancers detected. In addition to these figures, other aspects of the Programme are the subject of research, and information is published from time to time. The most recent example of this is the data on the occurrence of interval cancers in the North Western Region.[115]

69. In estimating the service requirements for the Screening Programme, the Forrest Report made certain basic assumptions which have formed the basis of the NHSBSP's own quality targets. In the initial three years of the Programme, during which time all women attending would be being screened for the first time, it was estimated that 70 per cent would accept the invitation for screening. Of those women who attended, about 10 per cent would be referred for assessment, about 1.5 per cent would be given biopsies and breast cancer would be detected in 0.55 per cent of cases.[116]

70. In the fourth and subsequent years, the Screening Programme would be dealing both with women who had reached the age of 50 during the previous three years (about 20 per cent of the total) and with women who would be attending for routine repeat screening. The Forrest Report estimated that, in the latter group, recall rates, biopsy rates and detection rates would be lower than in women attending for the first time, resulting in targets which would be slightly different from the targets for the first three years.[117] In 1993, the targets for the recall and biopsy rate were tightened in the light of experience, so the current NHS Breast Screening Programme targets are as follows:

- 70 per cent of women accept the invitation for screening;
- 7 per cent of women or fewer are recalled for assessment;

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[113]Nystrom *et al.*, Breast Cancer Screening with Mammography: overview of Swedish randomised trials, *The Lancet* vol 341, pp973-8.

[114]Chamberlain J, Firmer Evidence on the Value of Breast Screening — the Swedish Overview, *Eur J Cancer*, vol 29A, No 13, pp1804-5.

[115]Woodman et al, *BMJ* vol 310, p224.

[116]Op cit, p40.

[117]Ibid, p41.

- 1 per cent of women or fewer are given biopsies; and
- 5.5 cancers are detected per 1,000 women screened.[118]

71. Figures are available from the beginning of the financial year 1991-92, the first full year in which the Programme was fully operational, and show that overall, it is meeting its quality targets comfortably. The cancer detection rate has consistently been higher than Forrest's predictions: 6.2 per 1,000 in 1991-92 and 5.7 per 1,000 in 1992-93. The biopsy rate has fallen from 0.89 per cent in 1991-92 to 0.78 per cent in 1992-93 and the recall rate has fallen from 6.2 per cent in 1991-92 to 5.4 per cent in 1992-93. Despite the fall in the cancer detection rate, the number of small cancers detected has risen slightly. In 1991-92, 1,468 cancers were detected whilst they were still 1cm or less in diameter, representing 22.22 per cent of the total number of cancers detected. In the following year, 1,497 small cancers were detected — 22.69 per cent of the total.[119]

The Uptake Rate

72. The uptake rate has also consistently exceeded the quality target, but by a smaller margin, remaining steady at 71.3 per cent since 1991. However, this was subject to significant regional variation, from 60.1 per cent in North East Thames to 78.9 per cent in East Anglia.[120] Professor Vessey also told us that the Family Health Service Authority (FHSA) Registers, which are used as the basic list for inviting women for screening, vary significantly in accuracy from one area to another,

> "and that is especially true in inner-city areas, where they might be inaccurate to the tune of 30 or 40 per cent ... and there are a lot of women out there who have not been reached because the registers are inaccurate."[121]

This means that the uptake rates may in fact be lower than they appear, as they are based on the uptake rate amongst the population who receive invitations for screening, rather than the actual resident population. He went on to say that the Programme was working hard to generate interest in getting the registers right, amongst both women and GPs.[122]

73. Apart from the accuracy of FHSA Registers, the NHSBSP told us that the other factors which they had identified as affecting a woman's likelihood to attend for screening were her anxiety about screening and breast cancer, her previous experiences of screening (including breast screening), marital status (single women were less likely to attend), and the wording of the initial invitation.[123] A woman who receives an invitation to a particular appointment is much more likely to attend that a woman who receives an invitation asking her to contact the screening centre and make an appointment for herself.[124] **We were pleased to learn that the Programme is issuing guidance on the content of invitations, and we congratulate them on their mechanisms for disseminating best practice.**

74. Another point which the National Co-ordinator raised with us was the role of GPs in influencing the uptake. Patients tend to be called for screening in groups who are registered with the same GPs. Before a particular GP's patients are called, a representative from the NHSBSP visits the doctor concerned, explains what is going to happen and asks the GP to check the register for patients who have recently moved out of the area, or been diagnosed with breast cancer or with some other disease. Mrs Patnick told us that the attitude of a

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[118] *NHS Breast Screening Programme Review 1994.*
[119] Ibid.
[120] Ibid.
[121] Q65.
[122] Ibid.
[123] QQ66-8.
[124] Q67.

woman's primary care team was another one of the factors which influences a woman's decision whether to attend for screening.[125]

75. Doctors are asked to notify the local screening unit of any woman who has just joined their list and who may have missed the screening round. If a woman does not attend for screening, a note is sent to her GP, to be placed in her records, and remind the doctor to discuss it with her next time she visits the surgery. We believe that this is a good system, as it gives those women who have doubts about screening an opportunity to discuss them with their doctor, helping them to make an informed decision. In some cases a woman may have missed an appointment because she was on holiday or had pressing work commitments at the time, and she may require the help of her GP in organising an alternative appointment. We were therefore disappointed to learn that doctors occasionally ask,

"Why should I do this? I don't get paid for it and I do for cervical screening."[126]

76. Cervical screening and breast screening are not strictly comparable in this respect. In the case of cervical screening, the smear is often taken by the GP, whereas breast screening must be carried out with special equipment in a specialist unit. However, we do believe that doctors ought to discuss breast screening with their patients, to help them to reach an informed decision as to whether to attend or not. The National Co-ordinator suggested that there should be some financial incentive for GPs to encourage their patients to attend breast screening sessions.[127]

77. **Health promotion and health education are integral parts of general practice, and we are wary of any suggestion that GPs should receive any extra financial incentive to carry out such work. More importantly, the decision as to whether to attend for screening or not must rest with the woman herself, and we believe that the introduction of incentives for GPs to improve the uptake rate amongst their own patients might lead to doctors cajoling women into accepting screening invitations.** Nonetheless, the real uptake rates for the Screening Programme could be improved if FHSA Registers were more accurate, and we recognise that maintaining the accuracy of these registers and advising the NHSBSP of any recent new registrations and changes of address imposes a significant extra administrative burden on practices. **We therefore recommend that the Department of Health should examine, in conjunction with FHSAs, ways in which GPs might be assisted in undertaking the task of updating their registers prior to screening rounds, perhaps by the provision of extra, temporary clerical support at the time when their patients are being called for screening.**

The Number of Interval Cancers

78. The interim results reported by the NHSBSP are very promising. The Programme has exceeded its target for the proportion of women who attend for screening and the number of cancers detected. It has also kept to a minimum the number of women who are being recalled and who are receiving biopsies, and the targets for these figures have been further reduced from those originally proposed in the Forrest Report. There is, however, one cause for concern: the unexpectedly high number of cancers which are being reported in the intervals between screening.

79. Researchers from the Centre for Cancer Epidemiology and the Manchester Breast Screening Service studied 137,421 women who had received a negative screen between 1988 and 1992 in the North Western Region, and found that 297 of these women were diagnosed with breast cancer within three years of the screen. For women who received a negative screen between April 1989 and March 1990, 7.4 interval cancers were detected per 10,000 within the first twelve months, 9.4 per 10,000 after 12-23 months, and 13.5 per 100,000 after

[125] Q69.
[126] Ibid.
[127] Ibid.

24 to 36 months. This is significantly higher than would be expected on the basis of the Swedish evidence.[128]

80. The Government's immediate response to the problem was to make changes to the basic screening method which are designed to increase its sensitivity [see paragraphs 60 to 61], which should result in fewer cancers being missed at the basic screen. Professor Vessey told us that, if these measures were not successful, the Programme might have to consider reducing the screening interval and commented that most other programmes were based on a two-yearly rather than a three-yearly screening interval.[129] The Department of Health is currently conducting a trial to examine the effectiveness of reducing the screening interval, and the Chief Medical Officer told us that "it is illogical to change [the interval] until we have the evidence".[130] **We agree.**

The Screening Age

81. The Forrest Report said that

> "for any screening programme to achieve maximum efficiency it should be concentrated on those members of the population most likely to benefit from it. In the case of breast cancer this means those women who are most likely to develop breast disease and in whom the prognosis can be altered by screening."[131]

Although the Report recognised various risk factors associated with breast cancer, such as family history, early menarche, late menopause and late age at first full-term pregnancy, it concluded that age was the most important risk factor, and that "the use of risk factors other than age to identify women who should be screened is not practicable at present."[132]

82. The 50 to 64 age group was decided upon on the basis that there was no proven benefit in screening women outside that age range. In the Two Counties and Nijmengen studies, no difference in outcomes between the study and control groups was reported among women who were under 50 when they entered the trial. In the HIP trial, a reduction in mortality did begin to appear amongst women who were aged between 45 and 49 when they entered the trial, but only after six years (i.e. when they were aged 51 to 55). In those aged 40 to 44 at entry, a more modest effect became apparent after nine years (i.e. when they were 49 to 53).[133]

83. Professor Vessey of the Advisory Committee on Breast Screening explained why the trials may have shown little benefit from screening women under the age of 50.

> "In women in younger age groups the breast is much more dense and a much less satisfactory mammogram is obtained, there is more scope for confusion, in terms of detecting fewer of the cancers that are there, but equally important [are] the problems of ... false positives ... in premenopausal women, in younger women, the hormonal environment in the breast is different."[134]

The assertion that it is more difficult to obtain accurate, readable mammograms in younger women is borne out by the fact that the recall rate for women who are screened before the age of 50 is much higher than for women who are screened after the age of 50 (6.41 per cent, as compared to 5.41 per cent), although the cancer detection rate in that age group is lower (3.8 per 1,000, as compared to 5.7 per 1,000).[135]

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[128]Woodman *et al*, Is the three year breast screening interval too long? Occurrence of interval cancers in NHS breast screening programme's north western region, *BMJ* 310, p224.

[129]Q95.

[130]Q349.

[131]Op cit, p26.

[132]Ibid, p27.

[133]Ibid, para 5.4.

[134]Q93.

[135]*NHS Breast Screening Programme Review 1994*, p19.

84. Recent evidence from the Two Counties Study shows that there are other problems with screening women under the age of 50. Overall, the Two Counties Trial showed a 30 per cent reduction in mortality after 13 years of follow up, from screening women between the ages of 40 to 74. However, the reduction was 34 per cent for women aged 50 to 74, and only 13 per cent for women aged 40 to 49 years. Much of this difference was attributed to the shorter "sojourn time" in younger women. The sojourn time is the time during which the tumour is detectable by screening but is not producing any symptoms.[136] The suggestion was that many tumours in younger women tended to progress more quickly, and therefore, if younger women were to be screened, a one-year interval would be required for the programme to be effective. However, it is speculated that even yearly screening for women aged 40 to 49 would only have a little over half the impact on mortality as screening women over the age of 50 (19 per cent, as opposed to 34 per cent).[137] A recent article in *The Lancet* also concluded that "until further evidence becomes available, the issue of screening women [under the age of 50] does not warrant further discussion."[138] However, there may be some advantages to screening high-risk women under the age of 50. Professor Sikora told us that "What we are trying to do with the use of genetics is to ... see if we can identify people who have a much higher risk ... and then take them out and offer screening."[139] **We recommend that the Department of Health monitors the emerging evidence on this subject closely, with a view to implementing screening for high risk women under the age of 50, should it prove to be an effective approach.**

85. Despite his reservations about screening younger women, Professor Vessey admitted that the upper age limit of 64 was "much more iffy, it was iffy at the time that Sir Patrick's committee sat and it is still very iffy now."[140] The Forrest Report gave three reasons for its recommendation that screening should not be extended to women over the age of 64:

> "the lower acceptance of screening by women at older ages ... [the] increasing chance of [older women] dying of diseases other than breast cancer [and the fact that] breast cancer diagnosed in older women appears to run a less aggressive course than when diagnosed in younger women."[141]

86. The latter assertion is supported to a limited extent by the findings of the European Cancer Registry-based Study of Survival and Care of Cancer Patients (EUROCARE) study. In England, the relative ten-year survival rate of women who develop breast cancer up to the age of 54 is 54 per cent, and in women aged 55 to 64, it is 48 per cent. In women aged 65 to 74, relative ten-year survival is 52 per cent, and in women aged over 75, it is 50 per cent.[142] Age Concern England cited evidence from other sources suggesting that

> "almost without exception, the behaviour of common cancers is [neither] more nor less aggressive in older compared with younger patients."[143]

In fact, they argued that, however aggressive the disease in the elderly, older women with breast cancer may have a poorer chance of survival than their younger counterparts because of "stereotyped assumptions" about their treatments. They suggested that older women are disadvantaged in the treatment which they receive in two ways: there is a widespread misconception that older women cannot tolerate chemotherapy or radiotherapy, and the over-70s are routinely excluded from clinical trials.[144] If older women cannot tolerate more aggressive treatment, this is all the more reason to include them in the Breast Screening

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[136] Tabar *et al*, Efficacy of Breast Cancer Screening by Age, *Cancer* vol 75, No 10, p2507.

[137] Ibid.

[138] Wright and Mueller, Screening mammography and public health policy: the need for perspective, *The Lancet* vol 346, p29.

[139] Q326.

[140] Q93.

[141] Op cit, para 5.6.

[142] *Survival of Cancer Patients in Europe* (IARC, 1995).

[143] Ev p301.

[144] Ibid.

Programme in order to detect the cancers at an earlier stage, when less aggressive treatment is likely to be necessary.

87. The possibility that women over the age of 64 who are diagnosed with breast cancer are more likely to die of some other cause is also supported by the EUROCARE study. Whilst the relative ten-year survival of women over the age of 75 who are diagnosed with breast cancer is 50 per cent, the observed survival is only 15 per cent.[145] This means that 35 per cent of women in that age group died from other causes within ten years of being diagnosed as having breast cancer. In the 65 to 74 age group, 17 per cent of breast cancer patients died from other causes within ten years, but in the 55 to 64 age group, the equivalent figure falls to 7 per cent and in the 45 to 54 age group it is only 3 per cent.[146]

88. What is rather more difficult to understand is Forrest's assertion that there is "lower acceptance of screening by women at older ages".[147] Age Concern England pointed out that "the Two Counties (Sweden) study showed a 40 per cent reduction in breast cancer deaths among women aged 50-74 years, compared to a control group of the same age who were not offered screening."[148] The Forrest Report itself conceded that acceptance rates in the Two Counties study were over 80 per cent even up to the age of 74, citing only the Utrecht case control study as evidence that uptake rates were lower amongst older women.[149] This emphasis on the Utrecht study is puzzling. The Two Counties study recruited women aged 40 and over, whereas the Utrecht case control study recruited women aged 50 to 64. The evidence from Utrecht therefore indicates that women who attend for a first screen before the age of 65 are less likely to return for subsequent screens once they fall outside the upper age limit. The evidence from Sweden, on the other hand, showed that if there is no upper age limit on screening, 80 per cent of women continue to attend for screening at annual intervals up to the age of 74. As Age Concern pointed out, the Forrest Report "failed to set out in detail the results on which its conclusions on this topic were based [and] discounted the high uptake rate amongst women aged 65 to 74 found in the only large trial which included older women."[150]

89. The most recent evidence from the Swedish Overview indicates that screening is effective in women up to, but not beyond, the age of 69. The public health implications are summarised by Professor Chamberlain:

> "For populations with high breast cancer mortality, and with plentiful resources, provision of mammographic screening of women aged 50-69 is confirmed as a sensible public health policy."[151]

90. A further consideration not addressed in the Forrest Report is the cancer detection rate amongst older women. Breast cancer is much more common in older than in younger women — in 1989, there were a total of 8,752 new registrations of breast cancer in women aged between 50 and 64, whereas there were 11,179 amongst women over that age. A breakdown of new registrations of breast cancer by age is shown in Table 1. Dr Ian Fentiman of the Imperial Cancer Research Fund Clinical Oncology Unit of Guy's Hospital told us that in 1990 he had been asked to advise the Board of Health of the States of Guernsey on mammographic screening and suggested that it should be offered to all women over the age of 50.

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[145] Observed survival refers to the actual number of women who survived for the specified period of time. Relative survival discounts those women who died of causes other than breast cancer.

[146] *Survival of Cancer Patients in Europe* (IARC, 1995).

[147] Op cit, para 5.6.

[148] Ev p297.

[149] Op cit, para 5.6.

[150] Ev p300.

[151] Chamberlain J, Firmer Evidence on the Value of Breast Screening, *Eur J Cancer*, vol 29A, p1805.

"This advice was accepted and since then there has been a high uptake by the female population. As a result the pick-up rate of cancers has been twice as high as in the UK and this can be attributed largely to increased detection in older women."[152]

Table 1
Incidence of Breast Cancer by Age

Age Group	Registrations	Rate per 100,000
Under 1	2	0.6
1 to 4	1	0.1
5 to 9	1	0.1
10 to 14	1	0.1
15 to 19	3	0.2
20 to 24	24	1.2
25 to 29	157	7.8
30 to 34	427	24.6
35 to 39	963	57.3
40 to 44	1,912	105.5
45 to 49	2,334	160.4
50 to 54	2,477	181.1
55 to 59	2,842	214.7
60 to 64	3,433	257.5
65 to 69	3,606	253.4
70 to 74	2,673	254.4
75 to 79	2,808	274.5
80 to 84	2,092	285.0
85 and over	2,012	356.0
All ages	**27,768**	**107.2**

Source: 1989 Cancer statistics — registrations, England & Wales (OPCS)

91. Evidence from the NHSBSP itself shows that there is a higher detection rate in women aged over 65. In 1992-93, the Programme screened 22,036 women aged over 64 as a result of self referral or GP referral. Fourteen cancers per 1000 women were detected, or about 308 cancers in total. This compares with 6.2 cancers per 1000 self or GP referrals of women aged 50 to 64.[153] This comparison should be treated with some caution, as women whose GPs refer them for breast screening, or who refer themselves, are more likely to already have some kind of breast problem and are therefore more likely than asymptomatic women who are invited for routine screening to have breast cancer. It does not therefore provide a valid indication of the potential rate of detection afforded by an increase in the screening age.

[152]Ev p272.

[153]*NHS Breast Screening Programme Review 1994*, p19.

92. Age Concern's proposal, that the upper age limit for screening should be increased, was also supported by a number of bodies representing clinicians, including the Society and College of Radiographers,[154] and the British Medical Association. The BMA believed that the reason for lower uptake rates amongst older women was problems with the accessability of the service.[155] The Women's Nationwide Cancer Control Campaign told us that their helpline received a large number of calls from women over the age of 64 who wanted a mammogram, but did not know that they were still entitled to one on request.[156]

93. We are not convinced that Forrest's original concern about the uptake rates amongst older women is a compelling reason not to encourage women over the age of 64 to attend three-yearly screening. Even if the uptake rate were lower in older women, this would not necessarily be a good reason for excluding them from the call and recall system. Uptake rates vary according to a variety of factors, including geographical location,[157] social factors and ethnic group. The National Co-ordinator described these identified low-uptake groups as "harder to reach women."[158] She told us about the initiatives within the NHSBSP to promote screening amongst women whose first language was not English, women who were hard of hearing and women in inner cities, who have proved difficult to reach.[159] There has never been any suggestion that these groups should be excluded from the call and recall process simply because they exhibit low uptake. Instead, the Breast Screening Programme has worked hard to identify them and to draw them into the Programme. **We commend the NHS Breast Screening Programme on its efforts to improve the uptake rates amongst women who have hitherto not attended for screening, and we are confident that, if the screening age is increased, the same effort will be made to accommodate older women.**

94. The only one of Forrest's original reasons for drawing the line at 64 which is supported by the evidence is the increasing chance of older women dying of diseases other than breast cancer. We accept that this is the case, but we do not believe that it is a compelling reason for excluding older women from the programme, and we believe that it will become less compelling as longevity increases. A patient's age may be a consideration in the decision between doctor and patient as to what course of treatment to pursue. Baroness Cumberlege told us that

> "one of the things which the Forrest Report was concerned about was that the treatment of older women did not disadvantage them in as much as the treatment was so radical that in fact it was worse than the disease."[160]

We agree that this is a consideration to be taken into account in deciding on treatment, but we do not believe that it is a good reason for not attempting to detect the disease in the first place. In fact, if the disease is not detected until a late stage, the necessary treatment is likely to be more aggressive than if it is detected at an early stage.

95. The Chief Medical Officer told us that the Department of Health was conducting trials into the effectiveness of screening women under 50, reducing the screening interval and screening women over 65, and that evidence was expected at the end of the year.[161] We later learned that the study of the benefits of screening women over 65 is still in the planning stage.[162] **We believe that the Department of Health is quite right in wishing to base its screening policy on the latest sound evidence.** However, we do not believe that it is necessary to conduct *new* trials every time a change to the service specification is proposed. For example, this was not done when the Programme was first established.

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[154] Ev p236.
[155] Ev p244.
[156] Ev pp207-8.
[157] NHSBSP review 1994, p20.
[158] Q65.
[159] Ibid.
[160] Q348.
[161] Q349.
[162] *Official Report*, 18 May 1995, *c344w*.

96. We believe that there is already good evidence from the Swedish Overview that screening women up to the age of 69 is beneficial. Evidence from the Women's Nationwide Cancer Control Campaign suggests that allowing women over the age of 64 to attend for screening on request is not sufficient, as they are simply not aware that the service is available. **We therefore recommend that the upper age limit for inclusion in the call and recall system be extended to 69. We also believe that the Department of Health must ensure that women over the age of 69 are aware of their right to a three-yearly mammogram on request.**

The NHS Breast Screening Programme: Conclusions

97. The NHS Breast Screening Programme is a model service. It was established on the basis of firm evidence from randomised controlled trials and both the screening method and the quality targets have been modified since on the basis of new evidence and in the light of experience. **We believe that one of the strongest aspects of the Programme is its emphasis on quality assurance, and we believe that the QAP could provide useful lessons for the way in which the quality of other NHS services, including the management of symptomatic breast disease, might be improved [see section IV].**

98. The Programme has so far exceeded all its targets, based on those set out in the Forrest Report; it is therefore on course to contribute to the desired reduction in mortality. The only reservation which we have about its ability to meet this key target is the high number of interval cancers. We are pleased that the Programme has already been modified to reflect concern over this point and that evidence is being sought as to the effectiveness of screening women more frequently than every three years. **We recommend that, if it becomes apparent that a shorter screening interval is beneficial, the necessary resources will be made available to screen women more frequently, as long as this is not to the detriment of the symptomatic service.**

99. The uptake rate, whilst overall it exceeds the quality target, is a matter for some concern, as the original estimates in the Forrest Report did not take account of the incompleteness of FHSA Registers. We believe that the Department of Health needs to look at ways in which uptake might be further improved. In particular, GPs should be encouraged to be more active in educating women about the service, encouraging them to attend and helping those women who have missed a screening session to arrange a new appointment. A woman's GP is often the only medical professional with whom she has an ongoing relationship of trust, and he or she is the person best placed to help her to reach a decision about breast screening and to address her fears and anxieties. An even more important task for GPs is that of ensuring that their registers are up to date, and we believe that they should be given some assistance in this task [see paragraph 77].

100. More than 60 per cent of breast cancer deaths occur in women over the age of 64.[163] The present system under which women over the age of 64 are entitled to a mammogram on request is an unsatisfactory compromise. Whilst we appreciate that the evidence which was available at the time of the Forrest Report was not conclusive, we do not believe that, on the strength of the evidence from the Swedish Overview, calls to raise the upper limit for inclusion in the call and recall system can be resisted any longer, and we hope that an increase in the upper screening age to 69 will result in more cancers being detected at an early stage [see paragraph 96].

101. Screening alone can never be an effective strategy for reducing the mortality from any disease. There is little point in detecting breast cancer at an early stage if patients are not then going to receive the most appropriate treatment. There is evidence that treatment and outcomes vary considerably throughout the country. In the next section of this report, we discuss ways in which services for the clinical management of the disease might be improved.

[163] Ev p297.

IV. CLINICAL MANAGEMENT OF BREAST DISEASE

102. The NHS Breast Screening Programme, which is at the centre of the Government's plans to reduce the mortality from breast cancer, will not succeed on its own. Detecting breast cancer at an early stage will not produce any benefit in terms of reduced mortality unless all women with breast cancer, whether it is picked up by screening or through the development of symptoms, have access to the highest quality treatment. Unfortunately, we found evidence to suggest that the highest quality treatment is not available to all patients.

103. We heard proposals from the British Breast Group (BBG), a multidisciplinary forum for clinicians and scientists with a major interest in breast cancer, which were supported by a number of other witnesses, describing how a network of specialist breast units, consisting of a multi-disciplinary team of clinical specialists in the management of breast cancer, might be established across the country. **We recommend that in future, women with breast disease should be treated in such units, and we consider that a move towards treatment in specialist units would address several problems which we will now discuss.** First, we set out recent evidence which suggests that clinical outcomes and clinical practice are subject to variations from one area and one hospital to another. Next, we consider patients' views of the treatment which they have received — especially the complaint that their treatment was poorly co-ordinated and that they were badly informed by clinicians. We examine the components of high-quality care as defined by the Expert Advisory Group on Cancer to the Chief Medical Officers and the BBG, and the minimum standards of care proposed by the Cancer Relief Macmillan Fund. We then look at the Government's proposed new framework for commissioning cancer services and examine how a network of specialist breast units might be integrated into this framework. Finally, we look at ways in which a system of quality control might be introduced into a network of specialist breast units, by integrating the symptomatic breast cancer service with the NHS Breast Screening Programme.

Variations in Treatment: Evidence from the Yorkshire Region

104. A recent report by the Yorkshire Cancer Organisation provides some hard evidence to illustrate the wide variations between districts in the type of treatment which is offered to breast cancer patients.[164] A marked difference was observed in the number of women being treated by mastectomy (removal of the breast) and the number of women being treated by lumpectomy (removal of the tumour). Whilst the balance between the two types of surgery shifted in favour of lumpectomy over the period of the study (1976-1992), there was still a wide variation by district in the relative numbers of each operation. A woman who was offered surgery for breast cancer in Pontefract was 30 per cent more likely to have her entire breast removed than a woman who developed breast cancer in Dewsbury.[165] The Report commented that this was a cause for concern, as it was unlikely to be the result of differences in the stage of the disease at presentation.[166]

105. There were also significant variations in the type of adjuvant therapy being offered. Adjuvant therapies are those treatments which are given in combination with surgery, such as chemotherapy, radiotherapy and tamoxifen. Between 1988 and 1992, about 60 per cent of patients received radiotherapy in Hull, Pontefract and Wakefield, compared with 20 per cent in Bradford. This is a smaller variation than was in evidence in 1980, when less than 10 per cent of patients in Bradford received radiotherapy compared to over 80 per cent of patients in Harrogate.[167] Chemotherapy was offered to about 40 per cent of patients in York during the same period, but less than 25 per cent of patients elsewhere in Yorkshire, and whilst the use of hormone therapy grew steadily in all districts between 1976 and 1992, it was given to less than 60 per cent of patients in Grimsby, but over 90 per cent in Wakefield between 1988 and 1992.[168]

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[164] *Cancer in Yorkshire - Cancer Registry Special Report Series 3: Breast Cancer* (Yorkshire Cancer Organisation, 1995).

[165] Ibid, figure 22.

[166] Ibid, p19.

[167] Ibid, figure 24.

[168] Ibid, figures 19, 20, 25 & 26.

106. Slight variations in treatment are to be expected. Each woman will receive the treatment which she and her doctor believe is most appropriate for her. We have already discussed the possibility that the stage at presentation, aggressiveness of the disease and methods of collecting data vary from country to country and region to region [see paragraphs 25 to 27], but we find it hard to believe that the variation in these factors is so great between Pontefract and Dewsbury that it explains a 30 per cent difference in the number of surgical patients who are treated by mastectomy. Nor are they likely to vary so much between York and Grimsby that they explain a 30 per cent difference in the number of women being given chemotherapy. It is more likely that these variations in treatment indicate that, whilst some patients are receiving the most appropriate treatment for their condition, others are not, and specifically that adjuvant therapies, such as chemotherapy and radiotherapy, are under-used in some cases. The authors of the report suggest that "observed variations in survival might be explained by variations in management".[169] **We believe that the production and publication of this type of data on a national basis is essential to evaluate whether a network of specialist breast units does significantly improve patient outcomes.**

107. Dr Len Price, a Harley Street consultant physician and medical oncologist, elaborated on this point. He told us that

> "essentially, the position is that approximately four thousand women are dying every year because they are not being given treatment which is proven to be effective ... The use of adjuvant chemotherapy and hormone therapy in 'bad risk' patients has already saved more lives over the last fifteen years than any other single measure in the history of cancer medicine. Regrettably, most patients in the United Kingdom who might benefit from it never receive it."[170]

Clearly, there is a need to monitor clinical practice and clinical outcomes and to ensure that good practice is widely disseminated. We recommend how this could be achieved in paragraphs 150 to 156.

Patients' Experiences

108. The suggestion that clinical practice varies is borne out by what patients have told us of their own experiences. Dr Mary Armitage, a consultant physician with an interest in endocrinology and a breast cancer patient, told us that "the service is patchy [and] treatments variable, with little agreement between surgeons ... We could at least remove the uncertainties over management, by ensuring that every woman does receive the best care."[171]

109. Several patients mentioned lack of communication with doctors as being a particular problem. One patient mentioned the "lack of consultation and information, care or understanding [and] a failure to provide appropriate counselling."[172] Gwyneth Vorhaus, a breast cancer patient, also told us about doctors' unwillingness to communicate with her, and described the appalling manner in which she discovered that she had breast cancer. After having previously been told that she had a fibroadenoma (a form of benign breast lump), she was left waiting in a cubicle in an out-patient clinic for over two hours,

> "I finally wandered out into a room where a junior doctor was sitting looking at ... my X-ray ... The doctor looked very embarrassed. He turned his back to me and started muttering about 'microcalcifications and suspicious lesions'. I had to ask him to turn around and look at me. I said 'Are you trying to tell me I've got cancer?' He still could not use the word but his body language told me something was wrong ... I was left to wander off for an explanation from my GP."[173]

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[169] Ibid, p25.
[170] Ev p326.
[171] Ev p303.
[172] Ev p318.
[173] Ev pp19-20.

She also said that doctors "exhibited annoyance" when pressed for information.[174]

110. Members of Radiotherapy Action Group Exposure (RAGE) suggested that one of the main problems was not only lack of communication between doctors and patients, but lack of communication between the different doctors involved in the management of an individual patient, and Lady Ironside, giving evidence on behalf of RAGE, referred to the "lapses in procedure that occur between the doctor-to-doctor staging points in this pass-the-parcel network".[175] A patient experiencing damage to the brachial plexus (a network of nerves which runs down the upper arm) following breast cancer and adjuvant radiotherapy might be passed from GP to surgeon to physiotherapist to rheumatologist to neurologist to oncologist to orthopaedic surgeon and back to her GP with little consultation between the various professionals involved.[176]

111. Several of the patients who submitted evidence to us believed that their breast cancer had not been diagnosed quickly enough and that they had been treated by clinicians who were not sufficiently expert in dealing with the disease. The husband of one woman told us that she was initially told that her breast lump was benign, but that it turned out to be malignant twelve months later. In this case, the ultrasound scan and fine needle aspiration cytology were conducted by a junior doctor, but the files were overseen by a general surgeon rather than a breast cancer specialist.[177] Gwyneth Vorhaus told us that her GP referred her to a general surgeon and that her tumour was initially diagnosed as a fibroadenoma. She subsequently had to pay for a private consultation after the doctor who was treating her consistently denied that her persistent cough was the result of metastases in the lung. She suggested that diagnosis should be carried out by an oncologist specialising in breast cancer at a specialist cancer unit.[178]

112. A more specific complaint came from members of RAGE, all of whom had experienced extreme pain following radiotherapy for breast cancer. As Lady Ironside put it,

> "Something went dreadfully wrong in the treatment in the way that it was planned and delivered to us."[179]

The onset of the pain, which RAGE members believed to be the result of damage to the brachial plexus following radiotherapy, could occur up to 20 years after the treatment had been administered. They said that they were not given adequate warning about the possible side-effects of radiotherapy, that there was inadequate quality assurance in breast cancer treatment, that surgery should be performed by specialists and that their injuries might have been avoidable if there had been adequate quality assurance systems in place.[180]

113. A report last year by the Parliamentary Office of Science and Technology (POST) suggested that "the extent to which radiotherapy is responsible for such injuries is controversial."[181] Some clinicians would argue that it is well established that radiotherapy can damage nerve tissue (including the brachial plexus), and point to studies suggesting that between one and four per cent of breast cancer patients suffer from brachial plexus damage. Others point out that damage to the brachial plexus can be caused by a variety of factors, including the spread of the disease itself.[182]

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[174]Ev p20.
[175]Q169.
[176]Ev pp104-5.
[177]Ev p203.
[178]Ev p19.
[179]Q169.
[180]Ev p97 and Q182.
[181]*Radiotherapy and Cancer Treatment* (Parliamentary Office of Science and Technology, April 1994).
[182]Ibid, p9.

The Ten Minimum Standards of Care for Breast Cancer

114. The Cancer Relief Macmillan Fund last year launched a campaign based around ten minimum standards of care for breast cancer. The standards themselves are as follows:

"Every woman should have:

1. Prompt referral by a GP to a team specialising in the diagnosis and treatment of breast cancer, including a consultant from within the team.

2. A firm diagnosis within 4 weeks of being referred to hospital by a general practitioner.

3. The opportunity of a confirmed diagnosis before consenting to treatment, including surgery.

4. Access to a specialist breast care nurse trained to give information and psychological support.

5. Full information about types of surgery (including breast reconstruction where appropriate), and the role of medical treatments (eg radiotherapy, chemotherapy, tamoxifen, etc.)

6. A full explanation of the aims, risks and benefits of treatments proposed and possible side effects.

7. As much time as she needs to consider treatment options.

8. A sensitive and complete breast prosthesis fitting service, where appropriate.

9. The opportunity to meet a former breast cancer patient who has been trained to offer support.

10. Information on all support services available to patients with breast cancer and their families."[183]

115. Mrs Susan Butler of Macmillan explained that the aim of the campaign was to make every woman more aware of the kind of care she should expect from the Health Service should she ever be diagnosed with breast cancer, so that she could play a part in that care if she wanted to.[184] She went on to say that patients felt very vulnerable when they were diagnosed with breast cancer, and did not really know what to expect. They were often forced into a passive role, and did not know whether they were receiving good or bad care.[185] The minimum standards were designed to encourage good communication between patients and doctors — if patients know what kind of care to expect, they will be able to ask the right questions of their carers and play a more active role in the process.[186] Four million leaflets containing a small card with the minimum standards on it were distributed through large shops.[187]

116. It is important for women to have a good understanding of the kind of service which they should expect, and **we believe that Macmillan's minimum standards of breast cancer care provide a good indication for patients of the components of a high quality breast cancer service, and we congratulate the Cancer Relief Macmillan Fund on its campaign.** The standards complement the Government's seven principles of cancer care formulated by the Expert Advisory Group on Cancer to the Chief Medical Officers [see paragraph 117]. In

[183] *Breast cancer — How to help yourself* (Cancer Relief Macmillan Fund, 1994).
[184] Q268.
[185] Ibid.
[186] Q269.
[187] Q271.

many respects, the Macmillan minimum standards fulfil a similar role to that of the *Patient's Charter* — empowering patients by advising them of the standard of care which they are entitled to expect. **We therefore recommend that the standards be incorporated into the *Patient's Charter* as soon as possible.**

The Policy Framework for Commissioning Cancer Services

117. In April 1995, the Department of Health published its new proposals for the provision of cancer services.[188] The proposals were based on a report of the Expert Advisory Group on Cancer to the Chief Medical Officers of England and Wales, and were modified following public consultation. The proposed structure for commissioning cancer services is based on seven principles which should govern the provision of cancer care, which are worth setting out in full:

"(i) All patients should have access to a uniformly high quality of care in the community or hospital wherever they may live to ensure the maximum possible cure rates and best possible quality of life. Care should be provided as close to the patient's home as is compatible with high quality, safe and effective treatment.

(ii) Public and professional education to help early recognition of symptoms of cancer and the availability of national screening programmes are vital parts of any comprehensive programme of cancer care.

(iii) Patients, families and carers should be given clear information and assistance in a form they can understand about treatment options and outcomes available to them at all stages of treatment from diagnosis onwards.

(iv) The development of cancer services should be patient centred and should take account of patients', families' and carers' views and preferences as well as those of professionals involved in cancer care. Individuals' perceptions of their needs may differ from those of the professional. Good communication between professionals and patients is especially important.

(v) The primary care team is a central and continuing element in cancer care for both the patient and his or her family from primary prevention, pre-symptomatic screening, initial diagnosis, through to care and follow up or, in some cases, death and bereavement. Effective communication between sectors is imperative in achieving the best possible care.

(vi) In recognition of the impact that screening, diagnosis and treatment of cancer have on patients, families and their carers, psychosocial aspects of cancer care should be considered at all stages.

(vii) Cancer registration and careful monitoring of outcomes are essential."[189]

The *Policy Framework* goes on to propose a three-tier model of cancer care: primary care teams, which are seen as the focus of care; Designated Cancer Units in most district general hospitals, treating all the commoner cancers; and Designated Cancer Centres, treating the commoner cancers for their local population and the less common cancers by referral from Cancer Units.[190]

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[188] *A Policy Framework for Commissioning Cancer Services, A Report by the Expert Advisory Group on Cancer to the Chief Medical Officers of England and Wales, Guidance for Purchasers and Providers of Cancer Services* (Department of Health, 1995).

[189] Op cit, p6.

[190] Op cit, p7.

The Cancer Unit

118. The Cancer Unit will normally be a district hospital with a full range of supportive services. The Chief Medical Officer told us that "it is important to see the cancer unit not as a building but as a concept within the district general hospital".[191] The Cancer Unit will have arrangements for close integration of primary and secondary care, and for the rapid referral of patients who seem likely to have cancer. It should have a lead clinician responsible for organising and co-ordinating the whole range of cancer services, and a non-surgical oncologist who should also hold a position at the Cancer Centre.

119. The unit should have "site specific" clinics led by consultant specialists. These are clinics which deal with cancers in a particular part of the body, such as breast cancer and gastrointestinal cancer. The *Policy Framework* insists that

> "the most common cancers are initially managed by surgeons ... Surgical sub-specialisation in the common cancer sites within the Cancer Unit is essential and the hospital should only seek to function as a Cancer Unit if the volume of work related to each cancer site is sufficient to maintain such sub-specialisation. Similar considerations apply to the work of physicians in cancer care."[192]

In practice, this means that where there are several district hospitals in an area, purchasers and providers may agree between them that a cancer unit for certain cancers or groups of cancers will be established in one hospital, and for other cancers or groups of cancers in other hospitals. Rather that trying to treat every common cancer in every hospital in a given area, the quality of treatment could be improved by concentrating expertise and resources for particular cancers in particular hospitals. These specialist clinics may also treat non-malignant conditions. For example, women with non-malignant breast disease may be referred to the specialist breast clinic.[193] Whilst Cancer Units should be able to offer chemotherapy, radiotherapy would normally only be given in the Cancer Centre. Where Cancer Units are remote from the nearest Cancer Centre, the Units could provide a limited radiotherapy service in conjunction with the Cancer Centre.

The Cancer Centre

120. The Cancer Centre will be part of a large general hospital, which would provide services for patients with the commoner cancers in the same way as a Cancer Unit, but will also provide a range of specialist services in support of the local Cancer Units, including management of the rarer forms of cancer and "those treatment regimens which are too specialised, technically demanding or capital intensive to be provided by the Cancer Unit."[194] The hallmarks of a Cancer Centre are "a high degree of specialisation and comprehensive provision of all the facets of cancer care necessary in modern cancer management."[195] Most Cancer Centres will be able to offer services for paediatric and adolescent cancers, the management of rare cancers, specialist surgical services including plastic and reconstructive surgery, intensive chemotherapy, a full range of radiotherapy facilities, medical oncology, sophisticated diagnostic facilities and special expertise in palliative care and rehabilitation, although in the case of breast cancer, palliative care and rehabilitation may be offered in the Cancer Unit.

Primary Care

121. The *Policy Framework* emphasises the importance of the close relationship between primary and secondary care, describing it as "partnership in continuing care rather than the

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[191] Q327.

[192] *A Policy Framework for Commissioning Cancer Services*, p9.

[193] Breast cancer only accounts for about 10 per cent of breast disease.

[194] *A Policy Framework for Commissioning Cancer Services*, p15.

[195] Ibid.

permanent or temporary transfer of responsibility for the patient."[196] In order to judge the quality of care provided by local Cancer Units and Centres, GPs will require information on what constitutes best practice, both organisationally and for the management of individual cancers. They will also need guidelines on the management of symptoms which indicate a high risk of malignancy and will need to establish referral patterns in consultation with the hospital service. Secondary and tertiary care services should recognise that, whilst they are involved in the medical management of the patient, it is the patient's GP who will be providing psychological and emotional support. Communication between hospital and GP is therefore of paramount importance, and everybody involved in the patient's care will need to know of any changes in management.

122. **We welcome the guidelines set out in the *Policy Framework for Commissioning Cancer Services*, and we endorse wholeheartedly the seven principles of cancer care. We believe that the proposed three-tier structure for the provision of services for cancer patients, if it is implemented correctly, will serve to ensure that every patient does have access to the same high standard of treatment and support. We recommend that, if the proposed framework is to be implemented correctly, the Department of Health establishes a system of audit for Cancer Units and Cancer Centres.** We discuss this recommendation in more detail in paragraphs 140 to 146.

The Specialist Breast Unit

123. One of the most interesting points of the *Policy Framework* is the recommendation that

> "in future the surgical management of cancer should be carried out by consultant surgeons who specialise in a particular anatomical area."[197]

There is also a strong emphasis on multidisciplinary consultation and management, involving non-surgical oncologists, specialist nurses and radiographers.

124. A recent Report from the British Breast Group (BBG) has taken the idea of the management of breast cancer by specialist multidisciplinary teams further, proposing that all patients with breast disease, whether they have abnormalities detected on screening or go to their GP with symptoms, should be treated in a specialist breast unit.[198] Dr Michael Richards, the chairman of the working party which produced the Report, described its origins:

> "There was concern amongst the members of the group about the high mortality of breast cancer in the UK ... we were aware that the services for women with breast cancer were very widely dispersed in the UK with virtually every district general hospital undertaking breast cancer work. Within those hospitals it may not be one surgeon who focuses on breast cancer, so the services are very widely dispersed. We were aware of variations in treatment between different hospitals ... So there was concern about whether we had the right structure to provide optimal service."[199]

125. The aim of the Report was to demonstrate how breast cancer services in the UK could be improved by building on units which were already managing a substantial number of new cases of breast cancer each year and on the experience derived from the NHS Breast Screening Programme. It identified six characteristics of high quality care:

- accurate and timely diagnosis;
- appropriate treatment and follow-up;
- effective communication;

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[196] Ibid, p22.

[197] Op cit, p10.

[198] *Provision of breast services in the UK: the advantages of specialist breast units* (British Breast Group, 1994).

[199] Q17.

- access to other specialist facilities; and
- quality assurance, audit and research.[200]

126. The Report argues that multidisciplinary involvement in the management of breast cancer is essential at all stages. The initial assessment of a breast lesion would require clinical examination, breast imaging (mammography and ultrasound), pathology services (the examination of small pieces of tissue removed from the breast), and possibly surgical biopsy. Breast cancer, once identified, is primarily treated by surgery, but other treatments such as radiotherapy, chemotherapy and hormonal therapy will usually be offered. Access to all these services, and good communication between the professionals involved in the patient's care, and with the patient herself are essential.

127. The team itself would consist of a consultant surgeon, a consultant radiologist, a consultant histopathologist or cytologist, a consultant oncologist, a breast care nurse specialist, a chemotherapy nurse specialist and a diagnostic radiographer. Other professionals may be affiliated to the unit, such as a psychologist, a physiotherapist and a plastic surgeon, but would not necessarily form part of the core team.[201] All the members of the team should have training and expertise in the management of breast cancer, and they should hold regular review meetings involving all the core personnel. These meetings are necessary both to confirm diagnosis, and to prevent "ad hoc therapy being carried out by an individual acting without interaction with other members of the team."[202]

128. Mr Hugh Bishop of the British Association of Surgical Oncology (BASO) told us that the breast surgeon should take part in a diagnostic clinic which is dedicated to breast disease, rather than "a muddle of other surgical conditions", and should probably have a close association with the Breast Screening Programme.[203] He must be trained in breaking bad news and counselling. He should be expert in operating on breast cancer, on locally advanced and recurrent cancers. Dr Michael Richards of the BBG explained that the surgeon would be the "pivot" of the team in the early stages of assessment and in the primary treatment of the disease. Later in the course of treatment, the focus of care may shift towards the oncologist, and later still towards the palliative care specialist.[204]

129. One of the essential features of the specialist breast unit is that it needs a "critical mass" of patients — enough new cases of breast cancer to ensure that the members of the team maintain their expertise in dealing with the disease and to ensure that the units are cost-effective. The BBG Report points out that in some districts, as many as four hospitals are managing breast cancer, with each seeing fewer than 50 new cases each year. It proposes that each breast unit should see an absolute minimum of 50 new cases per year, but in general each unit should see between 75 and 100. For each new case of breast cancer, about eight or ten women with benign breast disease will be referred to the unit by GPs, so a unit seeing 100 new cases of breast cancer per year would see about 1000 patients per year in total, or about 20 each week. This would justify the provision of a weekly clinic for new patients, which would ensure that patients would not normally have to wait more than a week after being referred to the unit by their GP. In order to maintain this critical mass, some hospitals with a small referral practice would cease to manage breast disease, and this work would transfer to the local specialist breast unit.

130. Dr Richards told us that there were already several specialist units operating in the country, each dealing with up to 400 new cases per annum, but if each unit ended up dealing with an average of 100 new cases, there would be a network of about 250 units throughout the country.[205] Each unit would therefore serve a population of between 200,000 and

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[200] Op cit, p7 & Q17.

[201] *Provision of breast services in the UK*, pp13-14.

[202] Ibid, paragraph 4.3.

[203] Q28.

[204] Q29.

[205] Q32.

300,000 giving an adequate balance between convenience of access, and the necessary expertise for high quality care.[206]

The Advantages for Patients

131. It is worth examining how a specialist breast unit is able to deliver high quality care, as defined by the British Breast Group. One of the most basic advantages is the convenience of a "one stop shop": patients will not be passed "from place to place and from person to person in a pass-the-parcel system".[207] Each unit will see sufficient patients to hold a dedicated clinic for new patients each week, at which all the core team members will be present, and a woman will be able to receive a confirmed diagnosis at her first attendance at the clinic. Mr Bishop told us that

> "the majority of women should have their diagnostic tests done on the same visit ... they should not have to get a form for a mammogram, have it done two days later, have another thing [and] come back in two weeks' time."[208]

Rapid diagnosis is of utmost importance. In the case of a woman with breast cancer, it allows treatment to be given at the earliest opportunity, but in 90 per cent of cases, the woman is reassured that she does not have breast cancer, sparing her days, weeks or months of anxiety.

132. Patients who do have breast cancer will receive a high standard of care, as their care will be planned by a multi-disciplinary team. One of the suggestions in the Report of the Yorkshire Cancer Organisation is that adjuvant therapies are under-used [see paragraphs 102 to 107]. If treatment is planned by a team including an oncologist, rather than a general surgeon acting alone, women are more likely to receive the necessary adjuvant therapy. Dr Richards told us that he had received a telephone call from a colleague in another hospital, who wanted his advice on whether a patient should receive chemotherapy,

> "I said: 'Well, did she have positive axillary lymph nodes?' He said: 'The surgeons in this town unfortunately do not remove axillary lymph nodes.' I said: 'Well, was it pathologically grade three?' and he said: 'Unfortunately the pathologists in this town do not grade breast tumours'. I said: 'Well, what size was the tumour?' and he said 'Unfortunately that was not recorded in this case'. Those are the three factors I or any other oncologist involved in breast cancer needs to know if we are to make rational treatment decisions. That patient had been deprived of all that information to help somebody to make sensible judgments."[209]

This is one of the dangers inherent in a system in which patients are passed around between different professionals acting independently.

133. A further advantage would be good communication with patients. This was by far the greatest concern of the majority of patients from whom we received evidence. Effective communication with patients enhances their understanding of the disease and their ability to participate in treatment decisions. Each unit will have a nurse specialist to assist the consultants in breaking bad news and explaining the diagnosis and treatment options to the patient, and ensuring that the patient has the relevant written information. The regular team meetings, as well as providing an opportunity for audit and review, will also ensure that there is effective consultation and communication between everybody who is involved in the patient's care, and that whoever the patient is dealing with at any given time — the surgeon, the oncologist or the breast care nurse — will have a thorough understanding of her particular condition, treatment plan and personal needs.

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[206] *Provision of breast services in the UK*, p18.

[207] Ev p96.

[208] Q24.

[209] Ibid.

134. Communication with patients is a two-way street. It is as important for clinicians to understand the patient's needs and anxieties as it is for the patient to understand the disease and the treatment options. Nurse specialists have an important role to play in detecting psychosocial problems and determining patients' needs, and the breast care nurse is therefore an essential member of the team. Many units will also have an affiliated psychologist or psychiatrist. Mrs Sylvia Denton of the Royal College of Nursing told us that

> "there are studies that show that information has a positive effect on psychological morbidity and, indeed, women are perfectly capable of actually participating in choosing treatment options and it gives the feeling to a woman that they actually have more control over what is happening."[210]

The Evidence for Improved Outcomes

135. Despite the obvious advantages of convenience, communication and treatment by specialists, none of our witnesses was able to offer evidence that treatment in a specialist breast unit would improve patients' clinical outcomes. However, towards the end of our inquiry an article was published in *The Lancet*, which concluded that

> "Examination of differences in survival as a function of consultant caseload demonstrated poorer results amongst those surgeons treating less that 30 new cases of breast cancer per year ... We recommend that patients with breast cancer be dealt with only by clinicians who see more than 30 new cases per year and who have a full range of treatment options available within a multidisciplinary setting."[211]

This was the conclusion of a study of all female patients diagnosed with invasive breast cancer in the Yorkshire Region between 1979 and 1988 and treated by surgery of curative intent. The study found that consultants who managed 30 or more patients gave combined therapy (surgery with radiotherapy, chemotherapy and/or hormone therapy) to 76 per cent of their patients, whereas 38 per cent of patients who were treated by surgeons managing between 10 and 29 cases per year and 42 per cent of patients treated by surgeons who treated fewer than 10 cases per year were treated with surgery alone. Overall, there was no difference in survival between patients managed by consultants with caseloads of fewer than 10 patients per year and patients managed by consultants with caseloads of between 10 and 29 patients per year. However, patients who were treated by a consultant with a caseload of more than 29 patients per year had 30 per cent better survival.[212] This is evidence of the suggestions made in the BBG Report and by several of our witnesses: that breast cancer patients receive better care in units which see more cases of breast cancer.

Examples of Existing Units:
The Royal Marsden NHS Trust and St Mary's NHS Trust, Paddington

136. Several specialist breast units along the lines proposed by the BBG already exist, and we received evidence about the work of two of them. The Royal Marsden Hospital in London and Surrey has a particularly large breast unit, seeing 400 to 500 new cases of breast cancer each year, and a total of about 4,000 new patients. The multidisciplinary team consists of medical oncologists, clinical oncologists and surgeons, with associated specialist histopathologists. It is supported by a Consultant Liaison Psychiatrist and a Consultant Psychologist, and works in close collaboration with the hospital's own Palliative Care Unit. It is the largest "site specific" unit within the Royal Marsden, accounting for 47 per cent of the hospital's new registrations. It receives most of its patients from GP referrals, and others from consultants in other hospitals, the Occupational Health Department, the Breast Diagnosis Unit and from self-referral. The Medical Director, Mr R J Shearer, told us

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[210] Q287.

[211] Sainsbury, Haward, Rider, Johnston and Round, Influence of clinician workload and patterns of treatment on survival from breast cancer, *The Lancet* vol 345, p1265.

[212] Ibid, p1268.

"We believe that this pattern of multi-disciplinary care ... should be the norm ... We note and support the trend for purchasers to identify a minimum critical mass in breast cancer."[213]

We were pleased to learn that the Royal Marsden's own major purchaser, Merton, Sutton and Wandsworth, has indicated that provider units which are treating breast cancer should see at least 100 new cases per year.[214]

137. St Mary's Hospital, Paddington, conducted audits of its services for patients with breast lumps in 1992, 1993 and 1994, which revealed deficiencies in service provision. As a result, the St Mary's Hospital Breast Group was established in 1994. The Group is led by a Consultant Breast Surgeon and includes a radiologist, a histopathologist, an oncologist, two cytopathologists, a Breast Care Sister, a co-ordinator and a clinical audit facilitator. They operate a "one-stop" breast clinic, offering a same day breast lump assessment service. Within a week of referral by their GP, women see the Consultant Breast Surgeon and the Specialist Breast Care Nurse. Lumps are assessed according to agreed protocols, depending on the patient's age and family history of breast cancer, and all the necessary tests are performed on the same day. Patients are invited to return the same evening after 5.00 pm, when the Breast Care Nurse is available to explain their results to them and answer any questions which they may have. If they do not wish to return the same day, they can be telephoned the following afternoon, or the results can be sent directly to their GP.[215]

Cost Implications

138. The BBG Report calculates that, if each specialist breast unit were to treat an average of 100 new cases per year, a national network of about 250 such units, each serving a population of about 200,000, would be required.[216] Although many such units already exist, new ones would have to be established, and this would clearly have financial implications. The establishment of a network of specialist breast units would be a matter of reorganising and rationalising services rather than providing a great deal of new investment. Specialist breast units are likely to be established in those hospitals which already see a reasonably high number of new breast cancer patients each year. The Cancer Relief Macmillan Fund has already identified about 200 hospitals which either already have a specialist breast unit, or could establish one on the strength of their current volume of breast cancer patients. These units will be expected to take on more breast cancer patients and will therefore require more manpower, in-patient beds, theatre time and access to diagnostic facilities. However, these extra resources can be reallocated from the provider units which are would no longer be managing breast disease (generally, those hospitals which currently have only a small breast practice), and the reorganisation would therefore not have a major financial impact on individual hospitals.[217]

139. In fact, it is likely that a specialist breast unit would enjoy economies of scale not experienced by general surgical units treating breast cancer together with a variety of other cancers and other conditions. Mr Bishop of BASO told us that

"a specialist breast unit actually is more efficient. It does less benign breast operations, it does less unnecessary investigations ... and processes people more efficiently and in a more kindly way."[218]

There are likely to be both upward and downward pressures in costs resulting from more appropriate treatment. There is the possibility of reducing the cost of diagnosis and assessment, as more patients are offered fine needle aspiration cytology rather than open

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[213]Ev pp254-5.
[214]Ibid.
[215]Ev p273.
[216]Op cit, p3.
[217]Ibid, p17.
[218]Q27.

biopsy. On the other hand, the cost of treating patients may increase, as more chemotherapy may be offered to more patients who are capable of benefitting from it. One of the main suggestions in the two pieces of evidence from Yorkshire is that many patients are not receiving adequate chemotherapy.[219] However, increased chemotherapy costs would not necessarily be a matter for concern if they were a consequence of patients receiving more appropriate treatment. However, it will almost certainly be necessary to provide training for more specialist staff, and this will involve some genuine extra costs. We discuss the extra training costs for one group of team members, breast care nurse specialists, in paragraphs 161 to 166.

The British Association of Surgical Oncology (BASO) Guidelines

140. The *Policy Framework for Commissioning Cancer Services* sets out a three tier structure for the provision of cancer services, with most common cancers (breast cancer included) being treated in local cancer units with close co-operation with the patient's GP and back-up and specialist services from the local Cancer Centre. The Report from the British Breast Group identifies the main advantages and basic structure of a specialist breast unit, most of which would be in hospitals which were Designated Cancer Units within the new framework.

141. Two sets of guidelines for the management of breast cancer have recently been produced by the British Association of Surgical Oncology Breast Cancer Surgeons: one which relates to surgeons' role in the Screening Programme and one which relates to the surgeon's role in managing symptomatic breast cancer.[220] These guidelines complement the BBG Report and the *Policy Framework*, and set down auditable standards for the process of breast cancer care.[221] Mr Bishop of BASO told us that

> "We are not really saying anything very different [from the British Breast Group] ... This really represents the first time that surgeons have defined how they are going to measure the outcome of their activity."[222]

The two sets of guidelines lay down quality objectives or criteria such as "to ensure rapid referral", "all patients diagnosed with breast cancer should have access to a breast care nurse, preferably pre-operatively" and "to minimise the number of women requiring an open biopsy *for diagnosis*".[223] For each quality objective, there is a corresponding outcome measure, such as "Breast Units must establish multi-disciplinary designated 'Breast Clinics', for new patient referral", "All women with breast cancer must be given the opportunity to see a breast care nurse" and "less than 35 patients per 10,000 women receiving a prevalent screen [should receive an open biopsy for diagnostic purposes]".[224] **We have already discussed the importance of disseminating guidance on best practice in an earlier report, and we welcome the BASO guidelines.**[225]

The Specialist Breast Unit: Conclusions

142. The Government's *Policy Framework*, the recommendations of the BBG Report and the BASO Guidelines together constitute a detailed description of how a network of specialist breast units could be established. Hospitals with a low volume of breast cancer work will divest themselves of that work, and all breast cancer patients would be seen in specialist

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[219] *Cancer in Yorkshire — Cancer Registry Special Report Series 3: Breast Cancer* (Yorkshire Cancer Organisation, 1995) p25 & Sainsbury *et al*, Influence of clinician workload and patterns of treatment on survival from breast cancer, *The Lancet* vol 345, p1265.

[220] *Quality Assurance Guidelines for Surgeons in Breast Cancer Screening* (NHSBSP Publication No. 20, 1994) and *Guidelines for Surgeons in the Management of Symptomatic Breast Disease in the United Kingdom* (BASO, 1994).

[221] QQ30-38.

[222] Q37.

[223] *NHSBSP QA Guidelines for Surgeons*, p7; BASO *Guidelines for Surgeons*, pp6 & 13.

[224] Ibid.

[225] *Priority Setting in the NHS: Purchasing*, First Report of the Health Committee Session 1994-95 (HC 134-I), paragraphs 136-8.

breast units (usually within a Designated Cancer Unit), by a multi-disciplinary team of breast cancer specialists. These units would operate according to agreed protocols and auditable quality standards such as those laid down in the BASO Guidelines.

143. We found that there was overwhelming support for these proposals. RAGE told us that there should be a "one stop shop" for breast cancer patients and that all patients should be treated by breast cancer specialists rather than general surgeons.[226] Dr Mary Armitage told us,

> "I have studied carefully the British Breast Group's Report on the advantages of specialist breast units ... Almost every horror story, so beloved of newspaper reports and television, ends with ... [the woman's] previous management at a non-specialist unit being criticised."[227]

Breast Cancer Care supported the idea of "a hospital providing a multi-disciplinary team [including] a specialist breast surgeon, radiologist, pathologist and breast care nurse",[228] and the Dean of the Faculty of Clinical Oncology of the Royal College of Surgeons told us that "the future of breast cancer services is through specialist breast units and we feel sure that this is the way to reduce breast cancer mortality in the UK".[229] Finally, we were pleased that the Chief Medical Officer told us that the recommendations of the BBG Report and the BASO Guidelines should form the basis of nationally agreed guidelines for the management of breast cancer.[230]

144. **We agree entirely with the recommendations of the British Breast Group Report, we welcome the BASO guidelines, and we are pleased that they have received support from the Department of Health. We recommend that, in future, breast cancer should be treated in specialist breast units, by multidisciplinary teams of breast cancer specialists. As a first step towards implementing these proposals, we recommend that in hospitals where breast disease is managed within contracts for general surgery, separate contracts should be introduced, allowing purchasers to identify those hospitals which already have a high volume of breast cancer work and to begin the process of transferring breast cancer contracts to those hospitals.**

145. However, we also believe that it will be necessary to ensure that hospitals are not merely designated as specialist breast units, but have the necessary staff, expertise, facilities and volume of patients. The *Policy Framework* gives a broad outline of the kind of services which a Cancer Unit should offer, and describes the "hallmarks" of a Cancer Centre, but does not set out in any more detail what should be required in terms of the staff, expertise and facilities in each. The Chief Medical Officer told us that the new framework for cancer services would be based on

> "nationally agreed guidelines sufficiently flexible to be used locally ... That is much more effective than sending out a special national plan which says 'This is what you must do'."[231]

However, the Parliamentary Under Secretary of State for Health explained that the Regional Offices of the NHS Executive would have some ability to intervene if they felt that purchasers were not purchasing to the proposed framework.[232]

146. The setting of national standards is a question of finding a balance between the need to ensure that there is a uniformly high quality of service provision throughout the country

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[226]Ev pp94-104.
[227]Ev p303.
[228]Ev p188.
[229]Ev p191.
[230]Q328.
[231]Q328.
[232]Q331.

and the need to avoid stifling innovative local developments in the way that services are provided which, if successful, could lead to the adoption of superior practices throughout the country. We understand the concerns of Mr Chris Spry of South Thames RHA, who told us that a comprehensive system of national standards and accreditation would not be practical,[233] but **we note that the establishment of national, auditable standards for the NHS Breast Screening Programme has been very successful, and we believe that setting minimum standards for the provision of care in Cancer Units and Cancer Centres, and auditing those standards, is essential if the same quality of care is to be provided for all patients throughout the country.**

The Definition of a Specialist Breast Unit

147. The same problem also relates to specialist breast units. If breast cancer services are to be provided in specialist breast units, it will be necessary to ensure that they all meet the minimum standards in terms of members of the team, equipment and the facilities for administering different types of treatment. A definition of a specialist breast unit was recently proposed by an ad hoc group which included representatives of the Cancer Relief Macmillan Fund, the BBG, BASO, the Royal College of Radiologists Breast Group, the UKCCCR and the breast cancer groups of some of the Royal Colleges.[234]

148. The definition proposes that each unit should serve a population of between 200,000 and 300,000 people, seeing at least 100 newly diagnosed cases of breast cancer per year, and providing care for breast disease at all stages, from screening through to care of advanced breast cancer. The document defines minimum, mandatory requirements for the composition of the core team and suggests minimum service specifications similar to those set out in the BASO guidelines. In addition to these mandatory requirements, the document proposes several non-mandatory recommendations. These include participation in research, the provision of reconstructive surgery, and a physiotherapist or a breast care nurse with an interest in lymphoedema.[235]

149. **We believe that this kind of definition for the minimum service requirements for specialist breast units should be adopted by the Department of Health as a national standard. This may well be supplemented by separate standards of service provision for each site specific unit within the Cancer Unit or the Cancer Centre.** There will have to be some means of ensuring that units are meeting the national standards, and we believe that, in the case of breast cancer, this could be achieved by integrating specialist breast units with the NHS Breast Screening Programme.

Quality Assurance and Integration with the NHS Breast Screening Programme

150. The Quality Assurance Manager for Screening in the Northern and Yorkshire Region told us that

> "What is needed ... is a method of quality assuring the symptomatic breast cancer services in a similar manner to the quality assurance of the NHSBSP. There are many of us ... who feel that we could take on the quality assurance of the symptomatic service as well as the Screening Programme."[236]

Dr Armitage also reflected this view. She was worried that it might be difficult to ensure that all hospitals which claimed to offer a specialist breast service were actually providing one. She told us that "we should aim to have the same rigorous audit and co-ordination of [symptomatic] breast cancer services" as the Breast Screening Programme does.[237] Dr Richards told us that he would favour a national co-ordinator for all breast cancer services,

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[233] Q339.

[234] Ev pp191-7.

[235] Ev p196.

[236] Ev p205.

[237] Ev pp303-4.

not only screening, and Mr Bishop thought that such a development was "absolutely essential".[238]

151. There are two ways in which services for women with breast cancer are currently delivered. If a woman has a potential abnormality detected at an NHS Breast Screening Programme unit, she will be referred to a specialist team for assessment (in line with the recommendations of the Forrest Report), and in all probability be treated by that team, if cancer is diagnosed. Services for breast lump assessment for women with screen-detected abnormalities fall within the remit of the National Co-ordinator of the NHS Breast Screening Programme and the Quality Assurance Programme. She will therefore receive treatment from a specialist team in a unit which has an excellent system of quality control, sees a large number of patients and adheres to national guidelines and protocols.

152. If a woman goes to her GP with a breast problem, she will be examined in the GP's surgery and, if the doctor thinks that there is a likelihood that she has breast cancer (or benign breast disease which requires treatment), he will refer her to a consultant. This may be a unit that is associated with the NHS Breast Screening Programme, but it may equally well be the general surgeon at the local hospital, who is not a breast cancer specialist, does not work closely in a team with oncologists, radiographers and cytologists, sees only a few cases of breast cancer each year and is not subject to any external mechanisms for quality control.

153. The office of the National Co-ordinator of the NHS Breast Screening Programme and Regional QARCs have already have responsibility for maintaining high quality services for breast screening and assessment, according to explicit standards. There is already a great deal of expertise and specialisation amongst those who work in screening and assessment units and mechanisms are in place for audit and quality assurance to nationally agreed standards. **We believe that the overall standard of breast cancer care could be greatly improved by merging services for the management of breast cancer, including symptomatic breast disease, and the existing services of the NHS Breast Screening Programme.**

154. In practice, this could be done by favouring those hospitals which already operate screening units as sites for the establishment of specialist breast units, provided that they have a sufficient critical mass of new breast cancer patients. This will not be possible in all cases, as a screening unit will serve an average population of about half a million, whereas a specialist breast unit will serve a population of 200,000 to 300,000. The additional breast units could be developed in those hospitals which already see a high volume of breast cancer patients.

155. One such initiative is already taking place in North Thames RHA. They told us that they believed that "women should be offered the same standard of care from the breast service in both screening and symptomatic investigation and treatment."[239] They propose to extend the role of their Regional Quality Assurance Manager to include the symptomatic service, using quality indicators based on the number and training of staff in breast units, the volume of patients seen by each unit and the standard of care which is delivered.[240]

156. **We recommend that the Department of Health extends the remit of the office of the National Co-ordinator of the NHS Breast Screening Programme and Regional Quality Assurance Managers to encompass services for women with symptomatic breast disease, and issues national guidance to purchasers on the integration of the symptomatic service with breast screening. This will provide mechanisms for ensuring that best practice is followed in every unit throughout the country, and that every unit has the necessary staff, facilities and critical mass of patients and meets the basic minimum criteria laid down by the Department of Health. We also recommend that the QAP be used to provide evidence that the provision of specialist breast units is indeed leading to improvements in clinical practice and clinical outcomes.**

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[238] Q35.

[239] Ev p328.

[240] Ibid.

The Specialist Breast Unit: Other Considerations

The Macmillan Directory

157. Witnesses from the Department of Health pointed out that, if the existing network of specialist breast units were to be expanded, it would be necessary for GPs and patients to know where the units were and what services they were able to provide. Baroness Cumberlege told us that

> "I am sure that in future the demands are going to be very great on the service to give patients the information that they want. At the moment GPs are getting much more interested and are acting as a proxy to some extent but in future I am sure it is individuals who are going to say they want to go to the best unit, want to know which is the best unit and where the information is."[241]

The Cancer Relief Macmillan Fund has recently published a directory of breast cancer services in the UK.[242] For almost every hospital in the UK which deals with breast cancer, it gives information on which core personnel are available on and off site, the frequency of regular team meetings, the number of cases of breast cancer which are treated per year, the facilities on site (such as mammography, ultrasound, radiotherapy and chemotherapy), the time which patients have to wait for results, whether a breast care nurse is available to discuss their results with them, and whether the unit participates in clinical trials and the Breast Screening Programme.[243] It was designed primarily for GPs — to give them the information which they needed to refer their patients with breast problems to the best local unit — and was sent to all GPs in the country earlier this year.

158. The Directory was compiled by a survey conducted by Macmillan and the King's Fund.[244] Mr Douglas Scott, Chief Executive of Macmillan, told us that they had had "quite a lot of difficulty" getting responses out of hospitals.[245] The Directory was not audited, as no facilities for audit of breast units are in place, and there is no way of checking the accuracy of hospitals' reports of their own service. Dr Richards of the BBG told us that some of the replies may have been "a little optimistic", and the Directory itself notes that "some caution is required" in interpreting the data on patient numbers.[246] Despite the fact that there is no way of checking the accuracy of hospitals' data, **we welcome the Macmillan Directory and we believe that it is vital that GPs have this kind of information so that they know where to refer their patients. We hope that our proposals for extending the Breast Screening Programme QAP to cover therapeutic services for breast cancer patients will provide a mechanism whereby therapeutic services can be properly audited.**

159. Nonetheless, as the extension of the QAP will take some time to implement, we believe that it is necessary to ensure that the Directory continues to be revised, updated and made available to GPs. **We agree with Baroness Cumberlege, who told us that charities like Macmillan perform very valuable tasks, such as the production of the Directory, in partnership with the NHS, and we do not see any compelling reason for the Department of Health to take over production of the Directory, as long as adequate sponsorship is available in the charity sector.**[247] As Baroness Cumberlege told us, the Department of Health does not have "a monopoly of all wisdom and understanding".[248] However, **we believe that should any difficulty in funding arise, the Department of Health should ensure that sufficient funds are available to Macmillan to complete further editions of**

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[241] Q331.

[242] *The Macmillan Directory of Breast Cancer Services in the UK* (Cancer Relief Macmillan Fund, 1995).

[243] Ibid.

[244] Ev pp126-31.

[245] Q265.

[246] Op cit, pvii; Q37.

[247] QQ369-71.

[248] Q370.

the Directory. We were pleased that the Minister felt that the Macmillan would "have a good case" for section 64 funding.[249]

160. The Minister also told us that those hospitals which had not completed the questionnaire would feel ashamed when they saw the Directory and this would encourage them to respond the next time it is updated.[250] We believe that there is some truth in this, but that hospitals may also be tempted to over estimate their facilities and patient volume in future editions where they are slightly behind other local units. Mr Douglas Scott of Macmillan told us that the Department were very supportive of the Directory, but that "it might have been easier [to produce the Directory] if we had actually had ... written support from the Department."[251] **We believe that it might be helpful if the Department of Health were to send a covering letter with future editions of the questionnaire, emphasising the importance of supplying accurate details and underlining their official endorsement of the Directory. This would give greater authority to the project.**

The Role of Breast Care Nurse Specialists

161. All the core members of the specialist breast unit team are essential if it is to deliver the highest standard of care. We received a great deal of evidence on the importance of the breast care nurse within the team. While not wishing to play down the importance of other members of the team, we wish to endorse what we have heard about the special value of the breast care nurse's role.

162. Mrs Sylvia Denton of the Royal College of Nursing Breast Care Nursing Society defined a breast care nurse as "a clinical specialist in the area of the management of breast cancer."[252] She should have a sound knowledge of the disease and its processes, have the right personality and approach and the right "person spec" for the job. Mrs Denton emphasised the importance for breast care nurses of working in a team, as it is only through the team that they can access the services which a patient might need.[253] The work of a breast care nurse specialist goes beyond clinical nursing, although the nursing management of breast cancer and its complications (such as fungating lesions and lymphoedema) is part of the nurse's work. That work also includes offering information, helping the patient to understand her disease and treatment options, and offering emotional support.[254] Training for breast care nursing consists of a course in general oncology, followed by a course in breast care, which takes about six months in total. However, a breast care nurse's work also consists of helping to educate her colleagues, and updating her own education.[255]

163. As we have seen, poor quality information and lack of communication is one of the biggest complaints raised by patients about the quality of care they receive. A large part of the breast care nurse's role is supplying the information and the support which patients require [see paragraphs 108 to 113].

164. Many breast care nurses are funded by the Cancer Relief Macmillan Fund and Marie Curie Cancer Care. There are currently more than 1,300 Macmillan nurses in post, of whom 800 are based in the community and are known as home care nurses. Marie Curie Cancer Care runs training courses in breast cancer screening for practice nurses, and there are currently about 6,000 Marie Curie trained practice nurses in the country.[256] These figure includes nurse specialists in a variety of disciplines related to cancer care, including palliative care specialists, chemotherapy specialists and other "site specific" specialists, and there are

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[249]Q374. Under section 64 of the Health Service and Public Health Act 1968, the Secretary of State is empowered to offer financial assistance to certain voluntary organisations.

[250]Q374.

[251]Q293.

[252]Q296.

[253]Ibid.

[254]Q297.

[255]Q299.

[256]Q255.

currently 200 breast care nurse specialists in the country, of whom 92 are Macmillan nurses.[257] Macmillan nurse posts are set up in agreement with the employing NHS bodies and are funded by Macmillan during training and for the first three years of employment. After this period, the posts are fully funded by the employing NHS trust.[258] The average cost of a Macmillan breast care nurse is £81,000, which covers training (about £2,000), the first three years' employment (including employer's on-costs) and travel.[259]

165. When the network of specialist breast units is introduced, it will be necessary to ensure that there are sufficient numbers of breast care nurses to deal with the volume of patients in each unit. It is estimated that this will mean two nurses per average unit, within a system of about 200 to 250 units.[260] As there are already 200 breast care nurse specialists in post, this will mean training at least a further 200, at a total cost of approximately £0.5 million. We were pleased to learn from Mr Douglas Scott of Macmillan that they would be happy to continue providing their "pump-priming" grants for the next tranche of breast care nurses, and the total cost of the new nurses which will be required represents only about 5 per cent of Macmillan's total 1995 nursing budget.[261] **If it should become apparent, however, that sufficient funding is not available from the relevant charities to provide the required number of breast care nurses, we recommend that the Department of Health should consider providing additional funding to the charities which undertake training of breast care nurses in order to facilitate this.**

166. The question of whether there is an adequate number of specialist staff also applies to other professions involved in the management of breast cancer. For example, the Royal College of Radiologists told us that there was "a serious manpower shortage in clinical oncology", and the Society of Radiographers told us that there was a shortage of radiologists.[262] We have since learned that approximately 150 more radiologists would be required to specialise in breast disease, including about 70 new posts. It is likely that about 50 or 60 more surgeons will be required to specialise in breast disease and, to a lesser extent, more pathologists with an interest in breast cancer will be required.[263] **We recommend that the Department of Health should examine the staffing requirements of a network of specialist breast units and ensure, in collaboration with the relevant professional bodies, that sufficient specialist training is available.**

The Role of Primary Care

167. As the confirmed diagnosis and most of the immediate treatment for breast cancer patients is provided in the hospital setting, it is easy to overlook the role of primary care in managing breast cancer. The patient's GP will provide her with three main services: initial diagnosis and referral, ongoing support throughout the disease and advice and treatment for any other health problems which she may have.

168. The Royal College of General Practitioners told us that a patient with symptomatic breast cancer (or indeed with any breast lump) will be seen in the first instance by her GP, who will then refer her to a consultant. She will remain under the care of the GP throughout the time that she is attending the specialist breast unit, and will frequently attend the surgery with conditions other than breast cancer. Other members of her family may be registered with the same doctor, and he or she will play an important part in providing help, support and practical advice for the patient and her family throughout the course of the disease. Ultimately, it may be members of the primary care team who take responsibility for palliative care.[264] The average GP will only see about one woman with breast symptoms each month,

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[257] Ev pp137-8.
[258] Ev p137.
[259] Ev p139.
[260] Q311.
[261] Ev p137 & Q307.
[262] Ev pp191 & 237.
[263] BC 8D (not printed).
[264] Ev pp314-5.

and only one or two new cases of breast cancer each year. General practitioners do not see large numbers of women with breast disease, but it is important that GPs know when to refer patients with breast problems to a consultant for assessment and when to offer reassurance or adopt a policy of "watchful waiting". Reluctance to refer women for assessment may lead to cases of breast cancer being missed, but over-referral will lead to overburdened hospital clinics, which will not help to improve the management of breast cancer or to resolve patients' anxiety.[265] **We therefore welcome the Department of Health's proposals to issue referral guidelines for GPs in the management of symptomatic breast disease.**[266] We also believe that good communication between the specialist breast unit and general practitioners is of the utmost importance, and **we recommend that protocols for liaison between hospital breast specialists and GPs should be set out in the quality standards for specialist breast units.**

V. BREAST CANCER RESEARCH

169. We have not attempted during this inquiry to examine comprehensively the many issues surrounding research in the NHS. NHS research has recently been the subject of an report from the House of Lords Select Committee on Science and Technology, and it is a subject to which we may return in future inquiries.[267] However, we believe that research is an integral part of clinical practice, and it would be impossible to examine the way in which services for women with breast cancer are provided without also touching on the way in which clinical research is conducted. Medical research takes various forms — laboratory research, studies of the correlation of, for example, environmental and pathological factors and the incidence and prognosis of the disease, and the evaluation of promising new treatments in clinical trials. All these types of research are equally important, but in this report, we concentrate mainly on the importance of clinical trials, and make recommendations as to how some of the obstacles which currently impede such research might be removed.

170. As we have already seen, doctors' opinions about the best treatments for breast cancer vary. The value of good clinical research is twofold: it provides definite information about the comparative effectiveness of, and new uses for, existing treatments, and a means of assessing the value of promising new treatments. In 1993, a Department of Health report argued that

> "Research ... is not an isolated endeavour. It is an integral component of health and social policy, management, patient care and the delivery of social services."[268]

In cases where the effectiveness and safety of a treatment is unproven, doctors are unlikely to be keen to offer it to patients. One patient, Gwyneth Vorhaus, told us about such a treatment: high dose chemotherapy with stem cell rescue (HDSC). We believe that it provides a good example of the reasons why proposed new treatments must be submitted to rigorous testing.

171. High dose chemotherapy with stem cell rescue (HDSC) is a therapy which is still officially experimental in the USA, where it has been in use for ten years, but legal rulings mean that health insurance companies in many States cannot refuse to fund it for their customers.[269] Stem cells are generated in the bone marrow and multiply to produce more stem cells and white blood cells (which are involved in combating infection, wound healing and the rejection of foreign bodies). Very high doses of chemotherapy kill both white blood cells and stem cells, destroying the patient's immune system, and this is one of the factors which limits the dose of chemotherapy which can be administered. HDSC involves giving the patient a growth factor which causes stem cells to reproduce rapidly in the bone marrow

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[265] Mansel, Preece, Clarke, Sinnett & Austoker, *Guidelines for the effective management of breast conditions in general practice*.

[266] Q327.

[267] Third Report of the House of Lords Select Committee on Science and Technology, Session 1994-95, *Medical Research and the NHS Reforms* (HL 12).

[268] *Research for Health* (Department of Health, 1993), p3.

[269] Ev pp21 & 327.

and travel into the blood stream. The cells are then harvested and stored whilst the patient is given a very high dose of chemotherapy, after which the cells are replaced. Nonetheless, the patient must still be kept in isolation for about two weeks afterwards for fear of infection.[270] Gwyneth Vorhaus claimed she had been told that this treatment did not exist (by hospital doctors), that it was not indicated for breast cancer patients (by a cancer charity) and that the evidence from the USA for its effectiveness was over inflated (by "a respected British oncology professor").[271]

172. There is serious dispute about the effectiveness of the therapy. Gwyneth Vorhaus told us that evidence from the USA indicates that the treatment mortality is between 1 and 5 percent, that 20 per cent of patients with stage IV breast cancer (advanced breast cancer with metastatic spread) who are responsive to the treatment are cancer free after at five years and that 40 per cent survive longer than the two year median.[272] The treatment works best on patients who have already responded well to conventional chemotherapy, have a low cancer mass, have no bone marrow or nervous system involvement and are relatively strong.[273] However, she was keen to stress that

> "It is not a panacea; it is not a cure; it is not right in every case to have the treatment, but I would say it is right in a lot more cases than many doctors would tell you."[274]

Dr William Peters of the Duke University Medical Centre, North Carolina, one of the pioneers of the treatment, was slightly more cautious, telling us that "the evolving data is becoming sufficiently persuasive that the evaluation of patients in clinical trials of this approach should be hastened as quickly as possible."[275]

173. Dr Richards of the British Breast Group told us that

> "The available evidence indicates that a small proportion (possibly 5 to 10 per cent) of women who undergo high dose therapy/stem cell transplantation survive for longer than five years. The problem is to evaluate what proportion of women would have lived this long with conventional treatment ... My own interpretation of the data is that high dose therapy probably does improve the survival prospects among a highly selected group of women with metastatic breast cancer."[276]

He had recently referred one of his patients to a unit which specialised in high dose chemotherapy, and estimated that, out of 16,000 women who develop metastatic breast cancer each year, about 4,000 would be suitable candidates for the treatment. Of these, about 1,000 may not wish to have the treatment, and of the 3,000 who had the treatment about 150-300 would become long-term survivors. However, as the mortality from the treatment is currently about 5 per cent, about 150 patient would have their lives shortened as a result.[277]

174. Other witnesses were more critical of the treatment. Mr Richard Gray described the risks associated with the treatment as being "the same as playing Russian roulette", and Dr Howell of the UKCCCR told us that there was "absolutely no evidence that high-dose therapy is any better than the standard therapy."[278] He said that it would be unethical to tell a patient that a therapy was beneficial in the absence of any evidence.[279]

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[270] Ev p25.
[271] Ev p21.
[272] Ibid. The median survival time is the time at which 50 per cent of the patients in a defined group have died.
[273] Ev p25.
[274] Q48.
[275] Ev p327.
[276] Ev p2.
[277] Ev p3.
[278] QQ127 & 129.
[279] Q127.

175. From time to time, a treatment emerges from which the benefits are so great that controlled trials are unnecessary: antibiotics for lobar pneumonia, vitamin B_{12} for pernicious anaemia or insulin for diabetic coma. In these cases, the difference between using the treatment and not using it is the difference between life and almost certain death. Most medical advances, however, produce much more modest benefits — moderate, but welcome increases in survival. In the case of treatments such as HDSC, dispute is bound to exist about whether the proposed treatment is safe and effective and how it compares with conventional therapy. Some of our witnesses felt that the treatment might be promising, but most of them were reluctant to endorse its use because its effectiveness is as yet unproven. In these cases, our witnesses told us, the only acceptable standard of proof is the randomised controlled trial.[280] Mr Richard Gray of the Clinical Trial Support Unit and ICRF/MRC Cancer Studies Centre of the University of Oxford told us that

> "a ... realistic expectation of what treatments might achieve indicates the need for properly randomised evidence from apparently large numbers of patients that can discriminate between survival differences."[281]

176. New treatments undergo four phases of trials. Phase I trials are conducted on animals or small numbers of people to establish that there is no immediate toxicity; phase II trials are conducted on small groups of patients to give an idea of how effective the treatment *might* be; phase III trials are conducted on large numbers of patients, comparing the outcomes of those patients who receive the treatment with the outcomes of those patients who do not; and phase IV trials are conducted after a treatment has been introduced, to confirm the findings of the phase III trials and to establish what new uses the treatment might have. Dr Richards told us that phase III trials of HDSC have recently begun in the UK. Clinical research is often based on more basic research. Professor Barry Gusterson of the Institute of Cancer Research told us that several advances had been made recently in understanding the basic mechanisms of breast cancer. The first breast cancer susceptibility gene, BRCA1, has been identified, and a second, BRCA2, is under investigation.[282] He hoped that a better understanding of these genes would eventually enable superior drugs for the treatment and prevention of breast cancer to be developed. He suggested that a better understanding of the genetic and cellular changes involved in the development of breast cancer, if it were pursued in a clinical setting, could lead to improvements in the detection, diagnosis, prevention and treatment of breast cancer[283]. We now turn to ways in which the progress of research at the clinical stage could be expedited.

Randomised Controlled Trials

177. Mr Richard Gray told us that

> "If you just give a new treatment to patients and then compare [the results] with how they used to do then ... you have a bias between the patients that you give the new treatment and the previous patients."[284]

He said that the only way to avoid these "selection factors" was effectively to toss a coin so that half the patients received the promising new treatment and half the patients received the standard treatment. This eliminated bias in the selection of patients which might lead to patients with better or worse prognoses being given the new treatment.[285] Such a procedure is known as a randomised controlled trial. Dr Tony Howell of the United Kingdom Co-ordinating Committee on Cancer Research (UKCCCR) told us that a randomised controlled trial was "the only definitive way of telling whether [a new treatment] is better than the

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[280]See for example, Ev p2.

[281]Ev p45.

[282]Ev p269.

[283]Ibid.

[284]Q123.

[285]Ibid.

standard treatment"[286] We have already discussed several randomised controlled trials in breast screening, ductal carcinoma in situ and the prevention of breast cancer [see paragraphs 30 to 33, 62 to 63 and 65 to 66].

178. A randomised controlled trial is a means of comparing the effectiveness of two or more treatments, or of comparing the effectiveness of a treatment with the effectiveness of no treatment at all. Patients who agree to participate in such a study are randomly assigned to one of two groups: the "treatment" group or the "control" group. Patients in the treatment group receive the treatment which is being tested and patients in the control group receive either conventional treatment or no treatment at all. At the end of the trial, the outcomes of the two groups can be compared. If the patients in the treatment group fare significantly better than patients in the control group, this indicates that the treatment is more effective than conventional treatments. If they do not fare significantly better, then this indicates that the new treatment is probably no more effective than conventional treatments, and in cases where they fare significantly worse, the conventional treatment is superior to the new treatment.

179. It is important that the trial is *randomised*, as this eliminates the possibility that clinicians' prejudices about the treatment will lead them to select patients who in general have a better or worse prognosis into the treatment group. In some cases the trial may be "blinded" — conducted in such a way than neither the doctors nor the patients involved know which patients are in which group. This reduces the risk that doctors' or patients' beliefs about the effectiveness of the treatment will have an effect on outcomes. It is important that the trial is *controlled*, as the control group provides the basis of a legitimate comparison between the new treatment and existing treatments. In some cases (for example the DCIS trial) there may be more than one treatment group, and this allows the relative efficacy of several unproven treatments to be tested.

180. It is also important that the trial includes a sufficient number of patients to eliminate the play of chance. In many cases, this may involve thousands of patients — the DCIS trial aims to recruit 1,000 patients and the IBIS Trial aims to recruit 15,000. The Two Counties study and the HIP trial recruited 132,590 and 62,000 women respectively [see paragraphs 16, 31, 32 and 63]. Recruiting such large numbers of patients inevitably requires many hospitals to be involved, and such trials are known as "multi-centre trials"

Research Funding: The Role of the UKCCCR

181. In 1966, an editorial on cancer research in *The Lancet* concluded that

> "Two steps seem urgently needed: the Government must provide more money, and closer co-ordination of effort must be achieved between the organisations which support cancer research in this country."[287]

Four years later in 1970, the three bodies which funded the majority of cancer research, the British Empire Cancer Campaign (now the CRC), the Imperial Cancer Research Fund (ICRF) and the Medical Research Council, met for the first time within the formal organisation of the Co-ordinating Committee on Cancer Research, which was renamed the United Kingdom Co-ordinating Committee on Cancer Research in 1984.[288]

182. Membership of the main committee of the UKCCCR has expanded since its establishment, and it now includes representatives of all the main cancer charities and observers from the Department of Health and the Scottish Home and Health Department. The Committee's terms of reference are

"• to provide a forum for the exchange of information on the policies and plans of the bodies;

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[286] Q125.
[287] Ev p58.
[288] Ibid.

- to recommend proposals for the co-ordination of policies; and
- to advise the sponsoring bodies on any matters which might be put to the Committee."[289]

The UKCCCR works through a network of sub-committees, including the Cancer Screening Research Sub-committee and the Breast Cancer Trials Co-ordinating Sub-committee (BCTSC).[290]

183. For many years, the BCTSC was not directly responsible for running clinical trials but encouraged trial groups to collaborate wherever possible in preference to undertaking small, localised trials. Following the establishment of the NHS Breast Screening Programme, it became clear that ductal carcinoma in situ (DCIS) would become a relatively common diagnosis, and the UKCCCR took responsibility for the DCIS trial which is endeavouring to establish the best treatment for the condition [see paragraph 63]. Since then, the UKCCCR has endorsed the Adjuvant Breast Cancer (ABC) trial, a trial looking at the optimum duration of tamoxifen treatment (aTTom) and the tamoxifen prevention trial (IBIS). It is currently planning a trial of hormone replacement therapy in advanced breast cancer and the BCTSC has endorsed trials proposed by BASO for the treatment of other screen-detected small lesions.[291] Although it was not a UKCCCR project, a landmark in the history of breast cancer research was the decision to combine the data from all trials in breast cancer throughout the world in a meta analysis, known as the "Overview".[292] The Overview has produced firm evidence for the effects of adjuvant systemic therapies, and a number of current trials are examining questions which arose from it.

184. Although trials are endorsed and co-ordinated by the UKCCCR, they are still funded from a variety of sources. It is impossible to say exactly how much money is spent on breast cancer research each year, as the total amount spent by the pharmaceutical industry is not known. However, the Department of Health has told us that in 1992-93, the Government spent £3.8 million — £0.7 million through the Department itself and £3.1 million through the Medical Research Council (MRC). This was in addition to money supplied by the two main cancer research charities, £ 4.7 million by the Imperial Cancer Research Fund (ICRF) and £4 million by the Cancer Research Campaign (CRC). This brought total expenditure on breast cancer research to a total of £12.5 million, not including expenditure by drugs companies. As well as conducting their own research, companies may make contributions to clinical trials in the NHS. For example, the tamoxifen used in one trial is being supplied free of charge by the manufacturer.[293] Mr Gray told us that one large study had been funded with money which became available from the abandoned Strategic Defense Initiative in the USA.[294]

185. In its simplest form, a clinical trial is simply a matter of administering treatment to patients and collecting the outcome data. As much of this treatment is provided in NHS hospitals, the costs of the treatment should be borne by the NHS. However, significant extra resources are needed to enter patients into a trial. Patients must be given proper information about the trial, and this requires a great deal of clinicians' time in addition to the time usually spent advising patients about treatment options, risks and benefits. Patients may also need significant extra written information.[295] The data gathering itself requires a great deal of time, and most centres which participate in trials will therefore need a data manager, and once the data has been collected at the centres participating in the trial it must be compiled and

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[289]Ibid.

[290]Ev p59.

[291]Ev p47.

[292]Ibid.

[293]Ibid.

[294]Q155.

[295]See, for example, *Protocol of a Randomised Trial for the Management of Small Well-Differentiated and Special Type Carcinomas of the Breast* (BASO Breast Group, 1992), Appendix 2.

analysed in a clinical trials centre.[296] The processes of entering patients into the trial, collecting and analyzing the data add significant costs to trials, over and above treatment costs.

186. Given the co-ordinating role of the UKCCCR, and the fact that it represents most of the main sources of funding for breast cancer research, we were surprised to learn from Dr Helen Stewart of the UKCCCR that endorsement by the Committee or one of the sub-committees did not necessarily make a great difference to whether a proposed trial received funding. She told us that

> "Endorsement should help, but whether it makes a huge amount of difference is questionable."[297]

Mr Gray told us that, after a trial had been endorsed by the UKCCCR, researchers had to spend a lot of time "scraping around, trying to find where you can fund the research, it is becoming an increasingly large amount of one's time trying to seek funding."[298] Researchers had to go to the UKCCCR, the MRC, the CRC and the ICRF, as well as other organisations, and this might often involve going to 17 or more committees. Mr Gray pointed out that, ultimately, researchers were "at the mercy of the weakest of those committees, if they suddenly see fit to block it, and it is administratively very inefficient".[299] He told us that the biggest study of bowel cancer ever conducted, which involves every oncology centre in the country, had been running for a year and a half and had still not received funding.[300]

187. Not only are the current arrangements for funding research administratively very inefficient, but they undoubtedly costs lives. A delay of two years in securing funding for a trial of a promising new treatment for breast cancer which is subsequently proven to reduce mortality by five per cent will have resulted in over 1,000 deaths which could have been prevented if funds for the trial had been supplied more quickly.

188. Dr Stewart told us that if the UKCCCR had a separate budget for supporting clinical trials and research in breast cancer, it would make a tremendous difference to the trials scene.[301] Mr Gray also thought that it would be helpful if the UKCCCR had a budget of its own.[302] We believe that the funding of clinical trials in breast cancer would be greatly expedited if the UKCCCR, as the parent body in cancer research, were to have a budget of its own so that it could act as a "one stop shop" for the funding of trials. **Accordingly, we recommend that the Department of Health and the MRC should identify their budgets for clinical trials in breast cancer, and those budgets should be distributed through the UKCCCR. We believe that this would provide an incentive for the ICRF and the CRC to do likewise. We are mindful of the potential problems associated with a scheme whereby public funds are distributed through non-governmental bodies, and we do not believe that this system should be adopted until the Department of Health's status within the UKCCCR is upgraded from observer to full membership and proper facilities for auditing expenditure are in place.**

Ethics Committees

189. As well as committees which distribute funding, researchers proposing clinical trials must also seek approval from ethics committees. Ethics committees were developed in this country after the Royal College of Physicians recommended, in 1967, that clinical research should be the subject of ethical review. The MRC will not grant funding to projects which have not been the subject of ethical review, and some journals will not publish the results of

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[296] QQ157-63.
[297] Q156.
[298] Q155.
[299] Ibid.
[300] Q157.
[301] Ibid.
[302] Q158.

trials which were not approved by ethics committees. The functions of ethics committees are to facilitate medical research in the interests of society, to protect patients involved in research from possible harm, to preserve their rights and to provide public reassurance that this is being done. The composition of ethics committees varies from region to region, but they are generally widely representative bodies consisting of lay people, nurses, doctors and hospital managers.[303]

190. Local Research Ethics Committees (LRECs) must be consulted about any research involving NHS patients, foetal material and in vitro fertilisation (IVF) involving NHS patients, the recently dead on NHS premises, access to the records of past or present NHS patients and the use of, or potential access to, NHS premises or facilities. The Department of Health told us that LRECs advise NHS bodies whether a research proposal is ethical and that NHS bodies should not allow the research to proceed without such approval.[304]

191. Dr Stewart of the UKCCCR explained that one of the features of the progress of breast cancer research has been the move towards examining smaller and smaller sub-groups of patients and sub-groups of different tumour types which respond differently to different treatments. In such trials, it has become more important to involve a larger number of centres, as each centre will see fewer patients who fall within a defined sub-group. She told us that even when a trial had been endorsed at a national level, every individual centre participating in the trial would have to seek consent from its own ethics committee, and that this "puts people off from entering patients into trials [and] hampers progress within the Health Service."[305] Mrs Joan Houghton of the CRC Clinical Trials Centre told us that a large, multi-centre trial would have to be approved by more than 40 ethics committees.[306] Dr Stewart told us that "for something that is given national support and national endorsement, where large numbers of patients are required to get a valid answer ... perhaps there should be some pressure put on local ethics committees to accept that the study is ethical."[307]

192. Mrs Houghton described the situation in Denmark, where there are eight regional ethics committees. Where a multi-centre trial is operating according to national protocols, one of the regional committees takes the lead and makes recommendations to the others about whether to approve the trial or not. She thought it unlikely that other regional committees would reject the advice of the lead committee.[308]

193. The Department of Health told us that they shared our witnesses' concerns. Whilst they believed that the system worked well for the majority of research which involved only one or a small number of centres, it caused problems for large scale projects. They described the process of clearing a large, multi-centre trial through a number of committees as "time-consuming, expensive and frustrating when different LRECs give different decisions on, or seek different amendments to, the same proposal."[309] In cases where an LREC requests amendments to a protocol, this may effectively prevent a centre from participating in a trial, as significant variations in protocols from centre to centre may render the outcomes incomparable. The Chief Medical Officer is currently chairing a consultative group with a wide range of interests in medical research to examine how to improve the system of ethical review for multi-centre trials. It is considering three models: a locally-based model in which one committee gives a lead to others which may accept or reject it locally but may not amend it; a regionally-based model in which a lead committee in one region gives a national lead and

[303]Q142.
[304]Ev p168.
[305]Q142.
[306]Ibid.
[307]Q144.
[308]Q145.
[309]Ev p169.

a centrally-based model.[310] The CMO thought "it would be helpful to have some national view of the multi-centre trial to stop the bureaucracy."[311]

194. We believe that ethical review is an essential part of clinical research, and that some form of regional ethical review is desirable. Although the fundamental ethical considerations will not vary from region to region, there are local considerations, such as the languages in which information leaflets for patients are available, and the availability of appropriate facilities for the research at particular hospitals.[312] Equally, we believe that the progress of nationally endorsed, multi-centre trials should not be hampered unduly by ethical review, and we recognise the consensus of opinion that the research environment is changing and that systems of ethical review must change to match it. **We welcome the CMO's initiative to streamline the system of ethics committees, and we await its outcome with interest.**

NHS Indemnity

195. A further obstacle to conducting large-scale trials is the uncertainty over provision of indemnity for clinicians against legal action arising from clinical research. The Department of Health told us that NHS indemnity covers all employed health care professionals for negligent harm resulting from any research undertaken as part of their NHS contract, and that the employing NHS body (for example, the NHS Trust) is "expected" to bear the entire financial cost of defending and if necessary settling a claim where negligence is alleged.[313] They told us that "where there is no negligence, there is no liability", although the CMO described the question of indemnity for researchers as "a complex area ... in terms of negligence or non-negligent harm".[314] Ultimately, it is for the employing body to decide whether to allow research to proceed or not, and a Trust may decide not to allow its employees to participate in a clinical trial if, for any reason, it does not wish to provide indemnity for them.[315]

196. Mr Gray told us that many trusts were not allowing doctors in their hospital to take part in research unless they received indemnity cover from the study sponsors. Under guidelines issued by the Association of the British Pharmaceutical Industry (ABPI), studies which are sponsored by pharmaceutical companies receive automatic indemnity from the sponsors, but independent studies organised by the UKCCCR, the MRC and the cancer charities are not covered by those guidelines. Since many of the treatments being tested in independent trials are of little or no commercial value (for example, longer tamoxifen use and comparisons of radiotherapy and surgery), it is impossible to negotiate commercial indemnity.[316] The UKCCCR also told us that approval for trials was being withheld or delayed by Trusts in some cases while the question of who should provide indemnity was resolved, and the Department of Health told us that the MRC had provided them with anecdotal evidence of NHS Trusts requiring indemnity cover before research projects were allowed to proceed.[317]

197. In some cases, this has led to the absurd situation in which a doctor is permitted to use conventional treatment for patients with breast cancer, and is permitted to use new treatments in an ad hoc manner (even where there is no evidence as to which treatment is most effective), but is not permitted to assign patients randomly to treatment and control groups and to collect outcome data which ultimately will be of great benefit to the NHS.[318] Primarily it is concern about legal action rather than legal action itself which creates this kind

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[310] Ibid.
[311] Q377.
[312] Q378.
[313] Ev p166.
[314] Q377.
[315] Ev p242.
[316] Ev p46.
[317] Ev pp50 & 328.
[318] Ev p46.

of paradox. Mr Gray told us that, as far as he was aware, nobody had ever been sued for taking part in an MRC study.[319]

198. The Chief Medical Officer told us that

> "a group which brings together academic workers, the research councils, the CVCP, the Department of Health and the Department for Education, which met recently, decided that the best way forward ... was to set up a small working group ... to look at the whole question of indemnity."[320]

The Department later told us that exploratory meetings had yet to be arranged. We are pleased that the Department of Health has recognised that there are problems associated with the provision of research indemnity. However, large scale clinical trials are of benefit to the whole NHS. They provide the information on which the decisions of individual clinicians and health authorities about which treatments to offer are based, serving to exclude ineffective treatments and promote those treatments which are proven to improve patient outcomes.

199. The use of adjuvant systemic therapies such as chemotherapy and tamoxifen was described by one doctor as having "saved more lives than in the last fifteen years than any other development in the history of cancer medicine."[321] Their effectiveness was proven in large scale, randomised controlled trials.[322] The use of radical and super-radical mastectomy was shown, in large scale trials, to be of no greater benefit for women with breast cancer than breast conserving surgery, which is more acceptable for patients and has better aesthetic outcomes.[323]

200. Given that the benefits of clinical research are enjoyed throughout the Health Service, we do not believe that it is fair for indemnity cover for such research to be provided only by those units which participate in trials. **We recommend that comprehensive indemnity cover for NHS employees and NHS Trusts participating in independent clinical trials, approved by the relevant research bodies (for example, the UKCCCR in the case of cancer research), within the NHS should be provided centrally by the Department of Health.**

Specialist Breast Units and Research

201. We believe that the delivery of breast cancer care in specialist breast units will also have a beneficial effect on research. The concentration of more patients in fewer, specialist units will make it easier to conduct large scale clinical trials, as fewer units will be required to participate in each trial in order to recruit the required number of patients. The presence of a multi-disciplinary team will make it easier to conduct the kind of trials which examine the relative or combined efficacy of a variety of types of treatment, such as surgery, radiotherapy, chemotherapy and tamoxifen, and it can safely be assumed that breast specialists will have a greater interest in conducting research into breast cancer than general surgeons. However, one concern was raised by Mrs Joan Houghton of the CRC Clinical Trials Centre. She told us that they often experienced difficulty in getting specialist units to participate in large trials.

> "There are very few rewards for [clinicians] participating in multi-centre trials, except a lot of hard work and a lot of extra hassle ... It does not go on their CV and it is not acknowledged in their contract with the NHS."[324]

She believed that many units preferred to conduct their own, smaller-scale research, for which they received greater recognition and funding from outside bodies, especially in the case of

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[319] Q152.
[320] Q376.
[321] Ev p326.
[322] Q140.
[323] Q141.
[324] Q151.

academic units. We have already discussed the minimum standards for a specialist breast unit [see paragraphs 147 to 149], but we believe that it would be difficult to stipulate that units enter patients into trials as a minimum requirement, as the decision as to whether to enter into a trial or not rests with the patient. This is not to say, of course, that the research conducted in individual units is necessarily less valuable than multi-centre trials, and **we believe that the creation of more specialist breast units will make it easier to conduct both large, multi-centre trials and smaller scale clinical research involving only one unit.**

Involving Patients in Research

202. Mrs Hazel Thornton of RAGE told us about the work of a group which she founded: the Consumers' Advisory Group on Clinical Trials (CAGCT). The aim of the Group is

> "to foster a new attitude to research by working ... with the medical profession to provide quality research protocols of scientific merit but relevant to patients, which have been devised in a spirit of collaboration, with shared responsibility and public involvement."[325]

She said that the Group was demonstrating the benefits of patients working collaboratively with clinicians in the design of trials, most notably increases in patient recruitment to trials. If patients needs are accurately reflected in the initial design of trials, costly and time-consuming redesign of trials once they have begun can be prevented.[326]

203. After she was diagnosed with breast cancer, Mrs Thornton was offered an opportunity to participate in a trial, which she rejected on the grounds that the trial itself was "absurd".[327] She told us that if trials were imposed on women by the medical profession, they would find difficulty in recruiting patients because the patients could not identify with the questions which were being asked. She believed that the key components of any well designed trial were that it asked the right questions, that it asked the questions in the right manner, the provision of proper information and the involvement of patients at the design stage.[328]

204. Mrs Joan Houghton of the CRC Clinical Trials Centre told us that the kind of patient involvement which Mrs Thornton was proposing was an interesting aspect of breast cancer research which "those of us that have been involved in trials for a long time have not really resolved ourselves."[329] She said that patients had been involved in designing trials in pregnancy and neonatology for some time, but that this was not strictly comparable with a disease like breast cancer. Mrs Houghton and Dr Stewart both thought that one of the problems with consumer groups such as the CAGCT was that their members became very knowledgable about the conduct of clinical trials, and therefore less representative of the average patient.[330] Mrs Thornton also recognised that, because of her long involvement with, and understanding of, clinical trials, she was not strictly representative.[331]

205. It is important that patients are seen not as "guinea pigs" in clinical trials, but as full and active participants (albeit on a "different level" from clinicians).[332] We believe that patient involvement at all stages of a trial, including the initial design, is essential and that initiatives such as the Consumer's Advisory Group on Clinical Trials are to be welcomed. **We recognise that patients who have long-term involvement in such groups will acquire a knowledge base in excess of the average patient, but we believe that this kind of patient advocacy by a small group of well informed patients is far preferable to little or no patient involvement at all.**

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[325]Ev p108.
[326]Ev p109.
[327]Q203.
[328]Q203.
[329]Q149.
[330]QQ149-50.
[331]Q205.
[332]Q213.

VI. CONCLUSION: WHY BREAST CANCER?

206. Infectious diseases used to be one of the commonest causes of death in this country, but with the advent of modern antibiotics and vaccination, they have ceased to be a major public health problem. Smallpox has been entirely eradicated, diphtheria and polio have virtually disappeared, and other diseases such as meningitis and pneumonia are no longer invariably fatal. As mortality arising from these diseases has diminished, so other diseases for which there is no easy cure or method of prevention have come to present more of a threat. Cancer is an obvious example of such a disease. One person in three will now develop cancer, and one in four will die as a result.[333] As mortality from other diseases falls and longevity increases, these figures can be expected to rise.

207. Breast cancer is a particularly striking example. There is not as yet a sufficient understanding of its causes to render feasible attempt to reduce environmental risk factors, nor is there any proven method of prevention. Other cancers (such as lung cancer) generally have a worse prognosis and other cancers (such as bowel cancer) are more common. Cancer has multiple sites, presentations and complications and this makes it a major challenge to the NHS.

208. We hope that our recommendations will not be seen as being confined exclusively to breast cancer. Indeed, many of the recommendations in this Report relate to cancer in general, rather than exclusively to breast cancer [see paragraphs xx to xx]. There have been many recent developments in the way that breast cancer services are delivered which we would like to see followed up in the case of other site specific specialties. The NHS Breast Screening Programme is one example — it is possible that similar benefits might be demonstrated in screening for other cancers. The proposals for treatment in specialist breast units are another. **As those consultants and those hospitals which wish to concentrate on breast cancer divest themselves of work related to other cancers, the volume of patients with other cancers being seen by other consultants and other hospitals will increase, providing the necessary critical mass of patients to develop specialist lung cancer, bowel cancer, skin cancer, prostate cancer and head and neck cancer units.**

209. We believe that our recommendations will help to improve the standard of care for women with breast cancer in this country. We also hope that, as other specialties follow the lead, they may help to raise the standard of care for all cancer patients.

[333] *A Policy Framework for Commissioning Cancer Services* (Department of Health, 1995), p2.

SUMMARY OF CONCLUSIONS AND RECOMMENDATIONS

1. It is clear that the aetiology of breast cancer is not yet sufficiently well understood to enable any systematic attempt to reduce mortality by primary prevention to be pursued ... It is therefore all the more important to ensure that, in the case of breast cancer, adequate facilities for early detection and appropriate treatment are available (paragraph 16).

2. The most worrying explanation for the UK's apparently high mortality rates would be that they may be due, at least in part, to poor treatment of the disease (paragraph 26).

3. It is very difficult indeed, on the strength of the available evidence, to make good comparisons between breast cancer mortality in the UK and in other countries ... Nonetheless, we found widespread agreement amongst our witnesses that, even if the UK does not have the *highest* breast cancer mortality rate in the world, it has *one of the highest* rates. We believe that the Department of Health should commission research to establish how the UK's incidence and mortality rates compare with other countries, using a common method of measurement, and in particular to investigate the possibility that the disease in this country runs a more aggressive course than it does elsewhere (paragraph 27).

4. We believe that the Quality Assurance Programme is one of the great strengths of the NHS Breast Screening Programme. One of the most important aspects of the Quality Assurance Programme is its three-tiered operation at national, regional and local level (paragraph 50).

5. We believe that it is vital to preserve the NHSBSP Quality Assurance Programme and the Office of the National Co-ordinator in something like their present form following the dissolution of the Regions next April (paragraph 53).

6. The NHS Breast Screening Programme Quality Assurance Programme will only continue to be effective if its independence from the purchasers and providers of breast screening services is preserved. Lead district purchasing of the QAP is therefore potentially problematic, and the Department of Health must ensure that, if the transition to lead district purchasing is made in April 1996, quality assurance teams remain accountable to the national Programme rather than to their new purchasers. Even so, a system in which accountability does not follow funding is likely to be unnecessarily complicated, bureaucratic and unwieldy. We therefore recommend that the Department of Health give serious consideration to funding the QAP either directly by the NHS Executive, or by bottom-slicing from DHA allocations, and setting mandatory requirements for the standard of quality assurance which is to be purchased (paragraph 54).

7. The NHS Breast Screening Programme is sensitive to the problem of the anxiety caused to women who are recalled for further assessment and the National Co-ordinator described some of the steps which they have taken to reduce this kind of anxiety. They ensure that the recall letter does not arrive at the woman's home on a Saturday, when she is less likely to be able to seek advice and support from her own GP, and that the time between sending the letter and the appointment for assessment is only a matter of days. We believe that these are sensible precautions (paragraph 57).

8. We recommend that the NHS Breast Screening Programme examines, as a matter of urgency, ways in which patients who have breast abnormalities which are not believed to be cancer can receive a firm diagnosis more quickly, rather than be placed on early recall, and issues guidance to assessment units (paragraph 58).

9. We congratulate the Department of Health on its swift response to the higher than expected number of interval cancers, and we hope that both the number of false negatives and the number of false positives (and therefore the recall rate) will fall in future years as a result of these changes (paragraph 61).

10. We await the outcome of the DCIS trial with interest, and we note that the British Association of Surgical Oncology has already published guidelines, through the NHSBSP, for the management of screen-detected DCIS, based on the best available evidence at present.

However, we recommend that, once the comparative outcomes of the treatments under investigation are established, the Department of Health should issue, through the NHS Breast Screening Programme, guidance on best practice for the management of the condition (paragraph 63).

11. We were pleased to learn that the NHS Breast Screening Programme is issuing guidance on the content of screening invitations, and we congratulate them on their mechanisms for disseminating best practice (paragraph 73).

12. Health promotion and health education are integral parts of general practice, and we are wary of any suggestion that GPs should receive any extra financial incentive to carry out such work. More importantly, the decision as to whether to attend for screening or not must rest with the woman herself, and we believe that the introduction of incentives for GPs to improve the uptake rate amongst their own patients might lead to doctors cajoling women into accepting screening invitations (paragraph 77).

13. We recommend that the Department of Health should examine, in conjunction with FHSAs, ways in which GPs might be assisted in undertaking the task of updating their registers prior to screening rounds, perhaps by the provision of extra, temporary clerical support at the time when their patients are being called for screening (paragraph 77).

14. The Department of Health is currently conducting a trial to examine the effectiveness of reducing the screening interval, and the Chief Medical Officer told us that "it is illogical to change [the interval] until we have the evidence". We agree (paragraph 80).

15. We recommend that the Department of Health monitors the emerging evidence on genetic risk factors for breast cancer closely, with a view to implementing screening for high risk women under the age of 50, should it prove to be an effective approach (paragraph 84).

16. We commend the NHS Breast Screening Programme on its efforts to improve the uptake rates amongst women who have hitherto not attended for screening, and we are confident that, if the screening age is increased, the same effort will be made to accommodate older women (paragraph 93).

17. We believe that the Department of Health is quite right in wishing to base its screening policy on the latest sound evidence (paragraph 95).

18. We recommend that the upper age limit for inclusion in the call and recall system be extended to 69. We also believe that the Department of Health must ensure that women over the age of 69 are aware of their right to a three-yearly mammogram on request (paragraph 96).

19. We believe that one of the strongest aspects of the Programme is its emphasis on quality assurance, and we believe that the QAP could provide useful lessons for the way in which the quality of other NHS services, including the management of symptomatic breast disease, might be improved (paragraph 97).

20. We recommend that, if it becomes apparent that a shorter screening interval is beneficial, the necessary resources will be made available to screen women more frequently, as long as this is not to the detriment of the symptomatic service (paragraph 98).

21. We recommend that in future, women with breast disease should be treated in specialist breast units, and we consider that a move towards treatment in specialist units would address several problems which we discuss in paragraph 104 to 113 (paragraph 103).

22. We believe that the production and publication of data relating to regional variations in clinical practice and clinical outcomes on a national basis is essential to evaluate whether a network of specialist breast units does significantly improve patient outcomes (paragraph 106).

23. It is important for women to have a good understanding of the kind of service which they should expect, and we believe that Macmillan's minimum standards of breast cancer care provide a good indication for patients of the components of a high quality breast cancer service, and we congratulate the Cancer Relief Macmillan Fund on its campaign. The standards complement the Government's seven principles of cancer care formulated by the Expert Advisory Group on Cancer to the Chief Medical Officers. In many respects, the Macmillan minimum standards fulfil a similar role to that of the *Patient's Charter* — empowering patients by advising them of the standard of care which they are entitled to expect. We therefore recommend that the standards be incorporated into the *Patient's Charter* as soon as possible (paragraph 116).

24. We welcome the guidelines set out in the *Policy Framework for Commissioning Cancer Services*, and we endorse wholeheartedly the seven principles of cancer care. We believe that the proposed three-tier structure for the provision of services for cancer patients, if it is implemented correctly, will serve to ensure that every patient does have access to the same high standard of treatment and support. We recommend that, if the proposed framework is to be implemented correctly, the Department of Health establishes a system of audit for Cancer Units and Cancer Centres (paragraph 122).

25. We have already discussed the importance of disseminating guidance on best practice in an earlier report, and we welcome the BASO guidelines (paragraph 141).

26. We agree entirely with the recommendations of the British Breast Group Report, we welcome the BASO guidelines, and we are pleased that they have received support from the Department of Health. We recommend that, in future, breast cancer should be treated in specialist breast units, by multidisciplinary teams of breast cancer specialists. As a first step towards implementing these proposals, we recommend that in hospitals where breast disease is managed within contracts for general surgery, separate contracts should be introduced, allowing purchasers to identify those hospitals which already have a high volume of breast cancer work and to begin the process of transferring breast cancer contracts to those hospitals (paragraph 144).

27. We note that the establishment of national, auditable standards for the NHS Breast Screening Programme has been very successful, and we believe that setting minimum standards for the provision of care in Cancer Units and Cancer Centres, and auditing those standards, is essential if the same quality of care is to be provided for all patients throughout the country (paragraph 146).

28. We believe that a definition for the minimum service requirements for specialist breast units should be adopted by the Department of Health as a national standard. This may well be supplemented by separate standards of service provision for each site specific unit within the Cancer Unit or the Cancer Centre. There will have to be some means of ensuring that units are meeting the national standards, and we believe that, in the case of breast cancer, this could be achieved by integrating specialist breast units with the NHS Breast Screening Programme (paragraph 149).

29. We believe that the overall standard of breast cancer care could be greatly improved by merging services for the management of breast cancer, including symptomatic breast disease, and the existing services of the NHS Breast Screening Programme (paragraph 153).

30. We recommend that the Department of Health extends the remit of the office of the National Co-ordinator of the NHS Breast Screening Programme and Regional Quality Assurance Managers to encompass services for women with symptomatic breast disease, and issues national guidance to purchasers on the integration of the symptomatic service with breast screening. This will provide mechanisms for ensuring that best practice is followed in every unit throughout the country, and that every unit has the necessary staff, facilities and critical mass of patients and meets the basic minimum criteria laid down by the Department of Health (paragraph 156).

31. We welcome the Macmillan Directory and we believe that it is vital that GPs have this kind of information so that they know where to refer their patients. We hope that our

proposals for extending the Breast Screening Programme QAP to cover therapeutic services for breast cancer patients will provide a mechanism whereby therapeutic services can be properly audited (paragraph 158).

32. We agree with Baroness Cumberlege, who told us that charities like Macmillan perform very valuable tasks, such as the production of the Directory, in partnership with the NHS, and we do not see any compelling reason for the Department of Health to take over production of the Directory, as long as adequate sponsorship is available in the charity sector ... However, we believe that should any difficulty in funding arise, the Department of Health should ensure that sufficient funds are available to Macmillan to complete further editions of the Directory. We were pleased that the Minister felt that the Macmillan would "have a good case" for section 64 funding (paragraph 159).

33. We believe that it might be helpful if the Department of Health were to send a covering letter with future editions of the Macmillan questionnaire, emphasising the importance of supplying accurate details and underlining their official endorsement of the Directory. This would give greater authority to the project (paragraph 160).

34. If it should become apparent ... that sufficient funding is not available from the relevant charities to provide the required number of breast care nurses, we recommend that the Department of Health should consider providing additional funding to the charities which undertake training of breast care nurses in order to facilitate this (paragraph 165).

35. We recommend that the Department of Health should examine the staffing requirements of a network of specialist breast units and ensure, in collaboration with the relevant professional bodies, that sufficient specialist training is available (paragraph 166).

36. We welcome the Department of Health's proposals to issue referral guidelines for GPs in the management of symptomatic breast disease. We also believe that good communication between the specialist breast unit and general practitioners is of the utmost importance, and we recommend that protocols for liaison between hospital breast specialists and GPs should be set out in the quality standards for specialist breast units (paragraph 168).

37. We recommend that the Department of Health and the MRC should identify their budgets for clinical trials in breast cancer, and those budgets should be distributed through the UKCCCR. We believe that this would provide an incentive for the ICRF and the CRC to do likewise. We are mindful of the potential problems associated with a scheme whereby public funds are distributed through non-governmental bodies, and we do not believe that this system should be adopted until the Department of Health's status within the UKCCCR is upgraded from observer to full membership and proper facilities for auditing expenditure are in place (paragraph 188).

38. We believe that ethical review is an essential part of clinical research, and that some form of regional ethical review is desirable. Although the fundamental ethical considerations will not vary from region to region, there are local considerations, such as the languages in which information leaflets for patients are available, and the availability of appropriate facilities for the research at particular hospitals. Equally, we believe that the progress of nationally endorsed, multi-centre trials should not be hampered unduly by ethical review, and we recognise the consensus of opinion that the research environment is changing and that systems of ethical review must change to match it. We welcome the CMO's initiative to streamline the system of ethics committees, and we await its outcome with interest (paragraph 194).

39. Given that the benefits of clinical research are enjoyed throughout the Health Service, we do not believe that it is fair for indemnity cover for such research to be provided only by those units which participate in trials. We recommend that comprehensive indemnity cover for NHS employees and NHS Trusts participating in independent, UKCCCR approved clinical trials within the NHS should be provided centrally by the Department of Health (paragraph 200).

40. We believe that the creation of more specialist breast units will make it easier to conduct both large, multi-centre trials and smaller scale clinical research involving only one unit (paragraph 201).

41. We recognise that patients who have long-term involvement in patient advocacy groups will acquire a knowledge base in excess of the average patient, but we believe that this kind of patient advocacy by a small group of well informed patients is far preferable to little or no patient involvement at all (paragraph 205).

42. We hope that our recommendations will not be seen as being confined exclusively to breast cancer. Indeed, many of the recommendations in this Report relate to cancer in general, rather than exclusively to breast cancer. There have been many recent developments in the way that breast cancer services are delivered which we would like to see followed up in the case of other site specific specialties. The NHS Breast Screening Programme is one example — it is possible that similar benefits might be demonstrated in screening for other cancers. The proposals for treatment in specialist breast units are another. As those consultants and those hospitals which wish to concentrate on breast cancer divest themselves of work related to other cancers, the volume of patients with other cancers being seen by other consultants and other hospitals will increase, providing the necessary critical mass of patients to develop specialist lung cancer, bowel cancer, skin cancer, prostate cancer and head and neck cancer units (paragraph 208).

MINUTES OF PROCEEDINGS RELATING TO THE REPORT

Thursday 6 July 1995

Members present:

Mrs Marion Roe, in the Chair

Mr John Austin-Walker
Mr Hugh Bayley
Mr David Congdon
Alice Mahon
Mr Roger Sims

The Committee deliberated.

Draft Report, proposed by the Chairman (Breast Cancer Services), brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 209 read and agreed to.

Resolved, That the Report be the Third Report of the Committee to the House.

Ordered, That the Chairman do make the Report to the House

Several papers were ordered to be appended to the Minutes of Evidence.

Ordered, That the provisions of Standing Order No.116 (Select Committees (reports)) be applied to the Report.

Ordered, That the Appendices to the Minutes of Evidence taken before the Committee be reported to the House. — (*The Chairman.*)

Several Memoranda were ordered to be reported to the House.

[Adjourned to a day and time to be fixed by the Chairman.

LIST OF ABBREVIATIONS USED IN THE REPORT

ABPI	Association of the British Pharmaceutical Industry
BASO	British Association of Surgical Oncology
BBG	British Breast Group
BCTSC	Breast Cancer Trials Co-ordinating Sub-committee (of the UKCCCR)
BMA	British Medical Association
BSE	Breast Self Examination
BRCA1\BRCA2	Genes which are identified risk factors for some breast cancers
CAGCT	Consumers' Advisory Group on Clinical Trials
CMO	Chief Medical Officer (Department of Health)
CRC	Cancer Research Campaign
DCIS	Ductal carcinoma in situ
DHA	District Health Authority
FHSA	Family Health Services Authority
FNAC	Fine needle aspiration cytology
HDSC	High Dose Chemotherapy with Stem Cell Rescue
HIP	Randomised controlled trial of breast cancer screening by the Health Insurance Plan of Greater New York
ICRF	Imperial Cancer Research Fund
IBIS	International Breast Cancer Intervention Study
LREC	Local Research Ethics Committee
MRC	Medical Research Council
NHSBSP	National Health Service Breast Screening Programme
OECD	Organisation for Economic Co-operation and Development
OPCS	Office of Population Censuses and Surveys
QAP	Quality Assurance Programme
QARC	Quality Assurance Reference Centre
RAGE	Radiotherapy Action Group Exposure
RCT	Randomised controlled trial
RHA	Regional Health Authority
UKCCCR	United Kingdom Co-ordinating Committee on Cancer Research
UKTEDBC	United Kingdom Trial of Early Detection in Breast Cancer

LIST OF WITNESSES

LIST OF MEMORANDA INCLUDED IN THE MINUTES OF EVIDENCE

Published in HC 324-II

LIST OF APPENDICES TO THE MINUTES OF EVIDENCE

Published in HC 324-II

Page

UNPUBLISHED MEMORANDA

Additional memoranda have been received from the following and have been reported to the House, but to save printing costs they have not been printed. Copies have been placed in the House of Commons Library where they may be inspected by Members. Other copies are in the Record Office, House of Lords, and are available to the public for inspection. Requests for inspection should be addressed to the Record Office, House of Lords, London SW1. (Tel 0171-219 3074). Hours of inspection are from 9.30 am to 5.30 pm on Mondays to Fridays.

Cancer Relief Macmillan Fund [BC 3B & C]

Imperial Cancer Research Fund [BC 4]

CRC Psychological Medicine Group [BC 5]

The Royal College of Radiologists [BC 7A]

Professor Roger Blamey [BC 8A & D]

G E Medical Systems Limited [BC 9]

Sarah Cush [BC 12A-D]

British Association of Cancer United Patients (BACUP) [BC 13A-D]

Professor Michael Baum, Institute of Cancer Research [BC 23 A-M]

NHS Breast Screening Programme [BC 26A-D]

The College of Radiographers [BC 31A]

Department of Health [BC 32A & D]

Cancer Research Campaign [BC 42]

Age Concern England [BC 51A]

Professor R E Mansel [BC 52]

UK Co-ordinating Committee on Cancer Research [BC 55A-C]

The Institute of Cancer Research [BC 57]

Mammography Quality Standards Act of 1992, USA [BC 66]

Cancer in Yorkshire — Cancer Registry Special Report Series No.3, Breast Cancer [BC 73]

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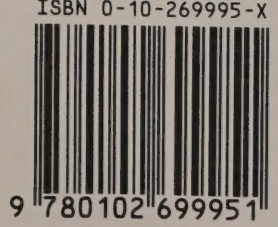

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